In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 04-394V
(To be published)

BRIAN and CLAIRE DEMPSEY, *parents of* K.J.D., *a minor*,	*	Filed: February 23, 2017
Petitioners,	*	
v.	*	Vaccine Act Entitlement; Causation-in-fact; Autism; Mitochondrial Dysfunction; Genetic Variant; MMR.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael McLaren, Memphis, TN, for Petitioners.
Ryan Pyles, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, ***Special Master***.

This is an action in which the Petitioners, Brian and Claire Dempsey, request compensation under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on account of their minor son, K.J.D., for injuries allegedly resulting from a measles-mumps-rubella ("MMR") vaccination administered on October 25, 1999. Petitioners allege that as a result of that vaccination of October 25, 1999, K.J.D. suffered from various neurological injuries, including complex epilepsy, epileptic encephalopathy, and developmental regression. Among K.J.D.'s neurodevelopmental conditions, he has been diagnosed with an autism spectrum disorder (ASD). For the reasons set forth below, I conclude that Petitioners are not entitled to an award.[2]

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2012 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2012 ed.). The statutory provisions defining the Program are also sometimes referred to as the "Vaccine Act."

[2] Although I have considered the entire record, including the voluminous medical records and medical literature, in arriving at my decision, I will only discuss evidence specifically relevant to resolution of this matter. *See Paterek v. HHS*, 527 Fed. Appx. 875, 884 (Fed. Cir. 2013). This includes medical literature submitted by both sides.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. §300aa-13(a)(1)(A); §300aa-11(c)(1)(C)(i); §300aa-14(a); §300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. §300aa-13(a)(1)(B); §300aa-11(c)(1)(C)(ii). ("Causation-in-fact" is also known as "actual causation.") In such a situation, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination initially caused, or significantly aggravated, the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination initially caused or aggravated the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or aggravation, but must demonstrate that the vaccination was at least a "substantial factor" in causing or aggravating the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" and the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id*. at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id*. at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11 v. HHS*, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

II

BACKGROUND: THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD")[3] were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs.

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[3] "Autism Spectrum Disorder" is a *general* classification which as of 2010 included five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term "autism" is often utilized to encompass *all* of the types of disorders falling within the autism spectrum. (*Id*.) I recognize that since the OAP test cases, the consensus description of ASDs, contained now in the "DSM-V" as opposed to the prior "DSM-IV," revises the prior subcategories of ASD set forth in the first sentence of this footnote. However, the DSM-V retains the same *general description* of ASDs. An ASD is a serious form of neurodevelopmental disorder defined by a collection of symptoms and behaviors, including significant impairment of social interaction and language skills, and the presence of repetitive, stereotyped interests. *E.g.*, *Snyder v. HHS*, No. 01-162V, 2009 WL 332044, at *31 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[4] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master file a decision denying their claim on the written record, resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in *rejection* of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g., Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28,

[4] The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

2012) (autism not caused by pneumococcal vaccination); *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Murphy v. HHS*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Corcoran Apr. 25, 2016) (autism not caused by DTaP or MMR vaccines), *aff'd*, 128 Fed. Cl. 348 (2016); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 9, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Holt v. HHS*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. Vowell June 24, 2015) (autism not caused by hepatitis B vaccine) (on review); *Lehner v. HHS*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. Vowell July 22, 2015) (autism not caused by influenza vaccine); *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by combination of vaccines); *Allen v HHS*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. HHS*, No. 03-632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine), *aff'd*, 125 Fed. Cl. 57 (2016), *aff'd*, 2016 WL 7174139 (Fed. Cir. Dec. 9, 2016); *Hardy v. HHS*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Hastings Nov. 3, 2015) (autism not caused by several vaccines); *Sturdivant v. HHS*, No. 07-788V, 2016 WL 552529 (Fed. Cl. Spec. Mstr. Hastings Jan. 21, 2016) (autism not caused by Hib and Prevnar vaccines); *R.V. v. HHS*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Corcoran Feb. 19, 2016) (autism not caused by influenza vaccine), *aff'd*, 127 Fed. Cl. 136 (2016); *Cunningham v. HHS*, No. 13-483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Hastings Aug. 1, 2016) (autism not caused by MMR vaccine), *aff'd*, (Fed. Cl. J. Smith Jan. 25, 2017) (not yet published); *T.M. v. HHS*, No. 08-284V (Fed. Cl. Spec. Mstr. Corcoran Aug. 9, 2016) (not yet published) (autism not caused by DTaP vaccine) (on review); *Anderson v. HHS*, No. 02-1314V, 2016 WL 8256278 (Fed. Cl. Spec. Mstr. Corcoran Nov. 1, 2016) (autism not caused by MMR vaccination) (on review).

In addition, some autism causation claims have been rejected *without trial*, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Fester v. HHS*, No. 10-243V, 2016 WL 1745436 (Fed. Cl. Spec. Mstr. Dorsey April 7, 2016) (autism not caused by measles, mumps, rubella, and varicella (MMRV) vaccine); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013) (autism not caused by multiple vaccines); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010) (autism not caused by multiple vaccines); *Miller v. HHS*, No. 06-753V, 2012 WL 12507077 (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014) (autism not caused by multiple vaccines); *Bushnell v. HHS*, No. 02-1648, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. Hastings June 12, 2015) (autism not caused by multiple vaccines); *Bokmuller v. HHS*, No. 08-573, 2015 WL 4467162 (Fed. Cl. Spec. Mstr. Hastings June 26, 2015) (autism not caused by multiple vaccines); *Canuto v. HHS*, No. 04-1128, 2015 WL 9854939 (Fed. Cl. Spec. Mstr. Hastings Dec. 18, 2015) (autism not caused by DTP and DTaP vaccines); *Valle v. HHS*, No. 02-220V, 2016 WL 2604782 (Fed. Cl. Spec. Mstr. Hastings April

13, 2016) (autism not caused by DTaP vaccine); *Hooker v. HHS*, No. 02-472V, 2016 WL 3456435 (Fed. Cl. Spec. Mstr. Hastings May 19, 2016) (autism not caused by multiple vaccines). Judges of this court have affirmed the practice of dismissal without trial in such cases. *E.g.*, *Fesanco v. HHS*, 99 Fed. Cl. 28 (2011) (Judge Braden affirming); *Canuto v. HHS*, No. 04-1128V, 2016 WL 2586510 (Fed. Cl. Apr. 18, 2016) (Judge Yock affirming), *aff'd*, 2016 WL 5746370 (Fed. Cir. Oct. 4, 2016).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.[5]

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[5] I am well aware, of course, that during the years since the "test cases" were decided, in two cases involving vaccinees suffering from ASDs, Vaccine Act compensation was granted. But in *neither* of those cases did the Respondent concede, nor did a special master find, that there was any *"causation-in-fact"* connection between a vaccination and the vaccinee's ASD. Instead, in both cases it was conceded or found that the vaccinee displayed the symptoms of a *Table Injury* within the Table time frame after vaccination. (See Section I above).

In *Poling v.* HHS, the presiding special master clarified that the family was compensated because the Respondent conceded that the Poling child had suffered a *Table Injury--not* because the Respondent or the special master had concluded that any vaccination had contributed to causing or aggravating the child's ASD. *See Poling v.* HHS, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cl. Spec. Mstr. Jan. 28, 2011) (a fees decision, but noting specifically that the case was compensated as a Table Injury).

Second, in *Wright v. HHS*, No. 12-423, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a "Table Injury" after a vaccination. However, she stressed that she was *not* finding that the vaccinee's ASD in that case was "caused-in-fact" by the vaccination--to the contrary, she specifically found that the evidence in that case did *not* support a "causation-in-fact" claim, going so far as to remark that the petitioners' "causation-in-fact" theory in that case was "absurd." *Wright v. HHS*, No. 12-423, 2015 WL 6665600, at *2 (Fed. Cl. Spec. Mstr. Sept. 21, 2015).

The compensation of these two cases, thus, does *not* afford any support to the notion that vaccinations can contribute to the *causation* of autism. In setting up the Vaccine Act compensation system, Congress forthrightly acknowledged that the Table Injury presumptions would result in compensation for some injuries that were *not*, in fact, truly vaccine-caused. H.R. Rept. No. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. ("The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.")

III

PROCEDURAL HISTORY OF THIS CASE

A. Petitioners' filing of a "Short Form Autism Petition"

Petitioners filed a Short-Form Autism Petition for Vaccine Compensation in this court on March 12, 2004. (ECF No. 1.) By filing that "Short Form" petition, Petitioners in effect alleged that K.J.D. suffered from autism, and that his autism was caused by either or both (1) the MMR (measles, mumps, rubella) vaccine, and (2) vaccines containing "thimerosal", a mercury-based preservative contained in a number of childhood vaccines until about 1999 (but removed from most childhood vaccines soon after that year). *Autism General Order #1*, Exhibit A, Master Autism Petition for Vaccine Compensation, 2002 WL 31696785, at *8 (Fed. Cl. Spec. Mstr. July 3, 2002). By filing the "Short Form" petition, the Petitioners also were, in effect, making their case part of the "Omnibus Autism Proceeding" (OAP). Thus, on March 19, 2004, this case, along with many others, was stayed indefinitely pending completion of the *general inquiry* under the OAP regarding the possible causal relationship between certain vaccines and autistic spectrum disorders. (*See* Section II of this Decision above.)

B. Petitioners' case status from July 2008 to December 2014

On July 15, 2008, I issued an order updating Petitioners on the status of the OAP and explaining how their case would proceed. (ECF No. 9.) Petitioners subsequently filed medical records (marked as Exhibits 1 to 20) on October 14, 2008. (ECF No. 10.) Thereafter, on November 19, 2008, Respondent filed a Motion to Dismiss, indicating that this case was not timely filed. (ECF No. 11.) The Petitioners subsequently filed their Opposition to Respondent's Motion to Dismiss on December 15, 2008, informing this court about their state court civil action filed prior to the filing of their Vaccine Act petition. (ECF No. 12.) On May 6, 2009, Petitioners filed a copy of their state court complaint, thereby showing that their Vaccine Act claim, "relating back" to the time of the state court filing, was in fact timely filed within the Act's statute of limitations. (ECF No. 19.)

On July 12, 2011, Petitioners were informed of the outcome of the OAP test cases, and instructed to determine whether they wished to pursue their claim further. (ECF No. 21.) Petitioners indicated that they wished to proceed. (ECF No. 22.)

I filed an order on March 13, 2013, requesting that Petitioners file additional medical records supporting their theory in this case. (ECF No. 30.) Over the next year, Petitioners requested several extensions of time to file medical records. (ECF Nos. 31, 33, 35, 38, 43, 45.) I granted these requests for extensions of time. (ECF Nos. 32, 34, 36, 39, 44, 46.) Petitioners were eventually able to secure attorney representation in this case, with the current counsel of record's motion for substitution being granted on March 12, 2014. (*See* ECF entry of 3/12/2014, granting a motion to substitute attorney.)

On May 20, 2014, Petitioners filed additional medical records (Exs. 21-22, ECF No. 54), and subsequently requested additional extensions of time to amend their petition and to file an expert report (ECF Nos. 55, 57). I granted those requests. (ECF Nos. 56, 58.)

C. Amended Petition[6]

On December 30, 2014, Petitioners filed an Amended Petition, alleging that the MMR, oral polio virus (OPV), and/or varicella vaccinations administered on October 25, 1999, caused the "development of epileptic encephalopathy, developmental regression, seizures, status epilepticus, and/or other injuries," in K.J.D. (ECF No. 59, p. 3.) Specifically, that Amended Petition alleged that shortly after the vaccinations of October 25, 1999, K.J.D. experienced "staring episodes related to seizures" -- episodes that later "developed into epilepsy and resulted in severe developmental regression." (*Id*., p. 4, ¶¶ 3-4.) Petitioners further alleged that K.J.D. "has two mutations in his CACNA1H gene" -- mutations that "made him susceptible to vaccine injury" -- thus, triggering "neurological deterioration that led to the development of complex epilepsy and developmental regression." (*Id*., p. 4, ¶¶ 5-6.)

Subsequently, on January 5, 2015, Petitioners filed the following exhibits: affidavit of K.J.D.'s mother, Claire Dempsey (Ex. 23); medical records from physician Amy Goldstein (Ex. 24); an expert report from Richard Boles, M.D. (Ex. 25); the *curriculum vitae* of Dr. Boles (Ex. 26); and corresponding medical literature (Exs. 27-33). (ECF Nos. 60-61.)

On April 9, 2015, Respondent filed an expert medical report by Gerald Raymond, M.D. (Ex. A), along with his *curriculum vitae* (Ex. B), and supporting medical literature (Ex. A, Tabs 1-10). (ECF No. 65.) Petitioners subsequently filed additional medical records on May 1, 2015. (Exs. 34-35, ECF No. 68.)

Pursuant to discussions during a telephonic status conference with Petitioners and Respondent on June 25, 2015, I reserved October 28, 2015, for a "fact hearing" in Pittsburgh, Pennsylvania. (*See* Order filed June 25, 2015.) Thereafter, a second "expert hearing" was scheduled for January 14, 2016, in Washington, D.C. (*See* ECF No. 71.)

Petitioners filed a supplemental expert report of Dr. Boles on July 27, 2015 (Ex. 36, ECF No. 72), later filing K.J.D.'s neurology records on September 9, 2015 (Ex. 37, ECF No. 73). On October 20, 2015, Petitioners filed additional affidavits of the "fact hearing" witnesses, Claire and Brian Dempsey (Exs. 38-39, ECF No. 75), later filing additional medical records (Exs. 40-42D, ECF No. 76) on October 26, 2015.

Thereafter, a "fact hearing" was held in Pittsburgh on October 28, 2015, during which Claire and Brian Dempsey testified.

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[6] Petitioners filed a "Motion to Amend Petition For Vaccine Compensation," attaching "Exhibit 1" labeled as "[Proposed] Amended Petition For Vaccine Compensation." (ECF No. 59.) For ease of reference, I will refer to this three-page "Exhibit 1" as the "Amended Petition."

Petitioners filed additional medical records on October 30, 2015 (Exs. 43-49, ECF No. 77); and subsequently filed digital video recordings (DVDs) showing K.J.D. from July to December of 1999 (Exs. 50-51, ECF No. 79). Both parties filed their respective prehearing submissions on December 18, 2015. (ECF Nos. 86-87). On January 12, 2016, Petitioners filed Ex. 54, which was comprised of selected video clips of K.J.D. from the DVDs that were previously filed as Exs. 50-53. (ECF No. 89.)

On January 14, 2016, a second evidentiary hearing was held in Washington, D.C., with testimony being heard from Petitioners' expert, Dr. Richard Boles, and Respondent's expert, Dr. Gerald Raymond. At the conclusion of the hearing, both parties informed me of their decision to forego post-hearing briefs. (2-Tr. 290-91.)[7] Thus, this matter is now ripe for a decision.

IV

FACTS

A. Facts appearing in K.J.D.'s medical records

1. Medical records concerning K.J.D.'s first year of life

K.J.D. was born on October 16, 1998. (Ex. 1, p. 1.) Over the first year of his life, K.J.D. seemed to develop normally, having an unremarkable medical history. (Ex. 34, pp. 1-10, 14-15). During his primary and regular well-child checkups, K.J.D. had no noted growth or developmental concerns, receiving his recommended vaccinations without any reported complications. (*See generally* Exs. 1-2; Ex. 34, p. 2.)

Notably, his family history reflects a sibling with an autism spectrum disorder (ASD), a father who underwent speech and language therapy, a grandfather with articulation problems, and maternal uncles with histories of language difficulties and potential learning disabilities. (Ex. 45, p. 3.)

2. K.J.D.'s medical records between 12 months and 18 months of age

At his twelve-month visit on October 25, 1999, K.J.D. was administered the measles-mumps-rubella ("MMR"), oral polio, and varicella vaccinations. (Ex. 34, pp. 2, 14.) On October 29, 1999, K.J.D.'s parents called his pediatrician to report their concern that he had a "pink eye" infection. (Ex. 1, p. 7.) K.J.D.'s medical records also contain a notation of a phone call on November 15, 1999, from K.J.D.'s parents, "want[ing] to speak to Regina." (*Id*.) (Mrs. Dempsey testified at the first evidentiary hearing that "Regina" is an employee in the office of K.J.D.'s pediatrician, who coordinated referrals to other doctors.) (1-Tr. 24-25.)

[7] I will refer to the transcript of the hearing on October 28, 2015, as "1-Tr.", and to the transcript of the hearing on January 14, 2016, as "2-Tr."

On November 22, 1999, K.J.D. was examined by his pediatrician for red eyes and green drainage. (Ex. 34, p. 13) During this visit, K.J.D. had a fever, was diagnosed with "Rom" (right otitis media, *i.e.*, ear infection), and was prescribed antibiotic medications. (*Id.*) Mrs. Dempsey subsequently called the pediatrician on November 26, 1999, wanting K.J.D.'s antibiotic medication changed due to reactions (*i.e.*, rash) from his then-prescribed antibiotic medication. (Ex. 1, p. 7; 1-Tr. 32-33.)

K.J.D. had a follow-up visit with his pediatrician to check his ears on December 7, 1999. (Ex. 34, p. 12.) He was no longer pulling his ears, but was noted to have "green matter from nose [and] eyes;" and his rash had improved. (*Id.*) On January 8, 2000, K.J.D. was seen by a pediatrician with a chief complaint of "can't hear," and this examining physician listed his ears as "perfect," but noted that K.J.D. had nose congestion, "URI" (upper respiratory infection), and hearing concerns. (*Id.*, p. 11.)

K.J.D. subsequently had a fifteen-month well-child visit on February 2, 2000. (Ex. 34, p. 19.) His examining physician noted that K.J.D. "tunes things out" and "acts as if in another world." (*Id.*) He was assessed with speech delay and was referred to an audiologist for further testing. (*Id.*)

A record dated February 3, 2000, from the developmental specialists "Babies Can't Wait," noted that K.J.D.'s mother expressed "concerns related to autism," and reported that "she has an older son diagnosed with something in the autism spectrum." (Ex. 40, p. 6.) In this record, Claire Dempsey described the condition of K.J.D.'s brother as "moderate to severe autism." (*Id.*, p. 8.)

One week later, on February 8, 2000, K.J.D was brought back to the doctor with complaints of crying and not sleeping the night before, as well as a runny nose and cough. (Ex. 34, p. 18.) The examining physician at that time diagnosed K.J.D. with a viral infection. (*Id.*)

K.J.D. underwent another assessment by Babies Can't Wait on February 22, 2000, and he was diagnosed as having developmental delay. (Ex. 40, p. 3.) Specifically, he was assessed as significantly delayed in the cognitive domain and moderately delayed in the communication domain, and his social and adaptive domains were listed as being "impacted by cognitive and communication delays." (*Id.*)

Another audiology assessment was performed on March 31, 2000, in which K.J.D.'s hearing test results were within normal limits. (Ex. 1, p. 65.) Within the "history" section of this examination, K.J.D.'s audiologist noted a "positive family history of speech and language problems" with K.J.D.'s older brother. (*Id.*) However, no other significant medical history relating to K.J.D. was reported by his parents. (*Id.*)

K.J.D. had his eighteen-month well-child examination on April 19, 2000. (Ex. 34, p. 20.) Within the "Parent's Comments" section of the examination form, Claire Dempsey indicated that K.J.D did not know five body parts; that he could not use a spoon; and that he did not have a vocabulary of eight to ten words. (*Id.*) K.J.D.'s pediatrician assessed him with speech and developmental delay. (*Id.*)

3. Medical records from 18 months to 3 years of age

a. Well-child checkups and routine sick visits

Throughout the remainder of 2000, K.J.D. was seen by his pediatrician for regular well-child examinations and for routine childhood illnesses. (Ex. 34, pp. 21-27.) Thereafter, from January to October of 2001, K.J.D was regularly seen by his pediatrician for unremarkable childhood illnesses such as: fever (*id*., p. 29); conjunctivitis ("pink eye") (*id*., p. 31); upper respiratory infection (*id*., pp. 31-34); teething (*id*., p. 32); and otitis media (ear infection) (*id*., pp. 31, 35-37).

b. Specialized care for K.J.D.'s developmental delay

On May 30, 2000, at nineteen months of age, K.J.D. underwent a speech assessment. (Ex. 3, pp. 5-10.) Regarding his developmental history at that time, Mrs. Dempsey reported K.J.D. reaching certain gross motor developmental milestones, such as rolling over at 4 to 5 months of age, sitting alone at 6 to 7 months of age, and walking at approximately 12 months. (*Id*., p. 5.) Further, she reported that K.J.D. spoke his first words at approximately 12 months, using around 1 to 5 words with some consistency at that time. (*Id*.) Mrs. Dempsey also reported that, after K.J.D. was administered the MMR vaccine of October 25, 1999, he "did not appear to be as focused and would not respond to his name consistently," and that "[s]he has been concerned since that time." (*Id*.) Mrs. Dempsey also stated concerns about K.J.D.'s feeding skills, and that he was often "defensive to the taste and texture of many foods." (*Id*.) Overall, K.J.D.'s pediatrician assessed him as demonstrating a "significant speech language disorder," with further concerns about his "reduced ability to explore his environment to gather information," "limited functional play," and "poor attention to tasks presented." (*Id*., p. 8.)

On June 14, 2000, K.J.D. underwent an occupational therapy assessment (Ex. 1, pp. 54-58),[8] which noted that K.J.D. demonstrated "delayed fine motor and self-help skills" (*id*., p. 57).

On January 18, 2001, K.J.D. was seen by a neurologist who recorded a history given by the family, which noted concerns that K.J.D. --

> showed normal language and motor development until his MMR immunization at one year. He was a baby who made lots of sounds and babbled frequently. This abruptly stopped following his immunization. He began having episodes of staring during which he was not responsive to loud sounds.

(Ex. 1, p. 45.) This neurologist assessed K.J.D. as having "autistic features including repetitive activity, language delay and impairment of social interaction," further noting that K.J.D.'s brother had similar features which had significantly improved over time. (*Id.*)

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[8] In this medical record, the date of evaluation is listed as "6/14/00" (Ex. 1, p. 54); however, the occupational therapist conducting the evaluation signed and dated the evaluation on June 26, 2000 (*id*., p. 58).

K.J.D. underwent another developmental evaluation on April 30, 2001. (Ex. 4, pp. 2-6.) At that time, K.J.D.'s parents once again gave a history reflecting that they first became concerned with his development at approximately 12 months of age. (*Id.*, p. 3.) Specifically, they noted that --

> shortly after he received his immunizations (MMR, varicella, OPV), he had a sudden change in behavior, seemed to be dazed, and displayed language regression. Following that, his developmental progress has been quite slow.

(*Id.*, p. 3.) At that visit, K.J.D. was tested on the Childhood Autism Rating Scale (CARS)[9] and was assessed to be within the "mildly-moderately autistic category." (*Id.*, p. 4.) Overall, his examining physician noted that K.J.D.'s behavioral profile is "consistent with a diagnosis of pervasive developmental disorder, autism." (*Id.*, p. 5.)

On October 18, 2001, K.J.D. saw Mary Megson, M.D., a developmental pediatrician. (Ex. 8, pp. 7-9.) Dr. Megson noted that, at three years of age, K.J.D. was non-verbal and that his parents believed that he "became autistic after his MMR vaccine." (*Id*., p. 7.) Dr. Megson's impression of K.J.D.'s condition was "[a]utism." (*Id*., p. 8.)

4. Medical records subsequent to three years of age (October 2001 to September 2015)

a. Routine visits and developmental therapy

Throughout this time, K.J.D.'s medical records reflect periodic physical examinations, sick visits for unremarkable illnesses, and continual developmental assessments. (*See, for example*, Ex. 1, pp. 14-17; Ex. 3, pp. 16-21, 56-63; Exs. 16, 19-20; Ex. 34, pp. 33, 38-41; Ex. 40, pp. 114-16; Ex. 41, pp. 11-27; Ex. 42.) Also during this time, K.J.D.'s parents continued to seek developmental treatment from speech pathologists (Ex. 16, pp. 1-3; Ex. 19, pp. 1-4) and occupational therapists (Ex. 19, pp. 5-10).

b. K.J.D.'s evaluation for gastrointestinal ailments

K.J.D.'s medical records reflect several treatments for gastrointestinal (GI) issues. However, in their Amended Petition and in the reports and testimony of their expert Dr. Boles, Petitioners did *not* allege that his gastrointestinal issues were vaccine-related.

c. K.J.D.'s medical history related to seizures

A letter dated July 26, 2004, from K.J.D.'s evaluating psychologist, Jane Kaufman, Ph.D., noted that K.J.D. was examined on April 16, 2004 to update his developmental status. (Ex. 20.) This letter noted that K.J.D. had experienced several seizures at some unspecified time

[9] "CARS," as defined within the Marcus Institute's Developmental Pediatric Initial Evaluation form, is "a 15 item behavioral checklist, designed to identify certain behavioral features present in children who have pervasive developmental disorder, autism." (Ex. 4, p. 4.)

in the past, and was "being stabilized on Trileptol" (an anticonvulsant medication). (*Id*.)

During an evaluation on September 13, 2004, Dr. Shelley Williams (one of K.J.D.'s treating neurologists after the Dempsey family relocated to the Pittsburgh area) recorded that K.J.D. was diagnosed in June 2003 with "[c]omplex partial epilepsy with secondary generalization" (Ex. 37, p. 9), a condition for which he initially presented with status epilepticus (prolonged seizures) (*id*., p. 12).

K.J.D.'s medical records reflect that he underwent several neurological examinations from March 2005 to January 2008, which showed, among other findings, K.J.D. having "idiopathic generalized epilepsy" in March of 2005 (Ex. 37, p. 2), and "seizures of partial onset with secondary generalization" in January of 2008 (*id*., p. 8).

A letter dated February 6, 2014, from K.J.D.'s current treating neurologist, Dr. Amy Goldstein, noted that K.J.D. was under her care for an "epileptic encephalopathy" and developmental regression. (Ex. 24, p. 1.) A medical record from September 3, 2015, reflected K.J.D.'s continued care by Dr. Goldstein for his seizure disorder. (Ex. 37, p. 21.)

d. K.J.D.'s genetic testing

K.J.D. underwent genetic testing by the Courtagen Diagnostic Laboratory on December 2, 2013, which identified a genetic variant within the CACNA1H gene. (Ex. 21, p. 1.) The corresponding genetic testing report generated by Courtagen stated that this CACNA1H gene variant was such that "while not sufficient to cause disease, may act as a modifying factor in the disease pathogenesis in this patient." (*Id*.) However, the same report later concluded that "this [CACNA1H] variant is unlikely to cause dominant disease and therefore is probably a benign polymorphism." (*Id*., p. 6.)

On February 6, 2014, Dr. Goldstein wrote a "Letter of Medical Necessity," in which she opined that mutations within the CACNA1H gene "confer a susceptibility to idiopathic generalized epilepsy." (Ex. 24, p. 1.) She concluded this letter opining as follows:

> I believe that [K.J.D.'s] mutations led to his susceptibility to vaccine injury and thus, developmental regression and epileptic encephalopathy, causing permanent neurodevelopmental disabilities.

(*Id*.)

B. Additional medical history reported by K.J.D.'s parents during this litigation

Both of K.J.D.'s parents provided written narratives, as well as testimony at the "fact hearing" on October 28, 2015, further describing K.J.D.'s clinical course. (Exs. 23, 38-39; 1-Tr. 4-94.) Overall, their recollection of events mostly agreed with what is reflected in the medical records. However, concerning the key facts surrounding K.J.D.'s *alleged severe reaction within week*s of his vaccinations of October 25, 1999, and the alleged onset of his seizures, the parents presented certain allegations which are at *variance* with K.J.D.'s contemporaneous medical records. I list these additional allegations below.

1. Claire Dempsey

a. K.J.D.'s condition in his first year of life

Mrs. Dempsey testified that K.J.D. was a happy and normal child during his first year of life, meeting all his developmental milestones. (1-Tr. 17-19.) She further relayed that prior to his vaccinations of October 25, 1999, K.J.D. was not reclusive or isolated (1-Tr. 28), was bright-eyed as he was smiling and laughing, and ate and slept well (1-Tr. 39-40).

b. K.J.D.'s condition between October 1999 and February 2000

Mrs. Dempsey provided testimony at the "fact hearing" about K.J.D.'s condition between October 25, 1999 (the date of his MMR vaccination) and February 2, 2000 -- *i.e.*, the time period prior to when the medical records began to document K.J.D.'s developmental issues.[10] (1-Tr. 23-25.) In her affidavit, she noted this time period to be of significance as it "was when all of [K.J.D.'s] medical problems began to happen." (Ex. 38, ¶ 14.)

Mrs. Dempsey testified that on November 15, 1999, 21 days after K.J.D.'s vaccination of October 25, 1999, she made a call to Regina, an employee in the office of K.J.D.'s pediatrician, who coordinated referrals. (1-Tr. 24-25; Ex. 38, ¶ 20; Ex. 1, p. 7.) She stated that she was prompted to contact Regina for an audiology referral for K.J.D. because Mr. and Mrs. Dempsey perceived what they thought was a significant decline in K.J.D.'s hearing. (1-Tr. 25-27.) Specifically, she testified that it seemed as if K.J.D. had gone deaf, as he was not hearing his name being called, was not moving when cabinets were slammed, and it was hard to get him to focus on anything. (1-Tr. 24-25.) K.J.D. was eventually seen by an audiologist in March of 2000. (Ex. 38, ¶ 27.) However, Mrs. Dempsey testified that between November 1999 and February 2000 (at which time K.J.D. was seen by his pediatrician for a 15-month well-child visit), he had intermittent hearing loss, lost focus, stopped smiling, and his development had stopped. (1-Tr. 27.)

Overall, Mrs. Dempsey testified about several of K.J.D.'s medical records during this time period -- a phone message for "pink eye" on October 29, 1999 (1-Tr. 31; Ex. 1, p. 7); the phone call to Regina for an audiology referral on November 15, 1999 (1-Tr. 23-25; Ex. 1, p. 7); a sick visit to K.J.D's pediatrician on November 22, 1999 (1-Tr. 31-32; Ex. 34, p. 13); a phone call on November 26, 1999, about a medication change due to K.J.D.'s allergic reaction to a specific brand of antibiotics (1-Tr. 32-34; Ex. 1, p. 7); a follow-up visit to the pediatrician on December 7, 1999 (1-Tr. 34-37; Ex. 34, p. 12); and a sick visit to the pediatrician on January 8, 2000 (1-Tr. 37-39; Ex. 34, p. 11).

[10] As previously noted, the first mention of K.J.D.'s developmental issues is contained in the records of K.J.D.'s 15-month well-child visit on February 2, 2000. (*See* Ex. 34, p. 19.)

In her affidavit, Mrs. Dempsey also asserted that K.J.D. began to have "absence seizures" (her affidavit called them "absent seizures") during this time period, but that she was unaware at the time that this behavior constituted seizures.[11] (Ex. 38, ¶ 15.)

Her affidavit further described K.J.D.'s alleged changes post-vaccination, relaying that he was not eating normally, had a weakened immune system, had diminished eye contact, and that there were instances during which she and her husband suspected that K.J.D. was deaf. (Ex. 38, ¶ 27.)

c. K.J.D.'s declining condition over time

Mrs. Dempsey further asserted that as time progressed, K.J.D.'s staring spells worsened, he had severe learning deficits, and was having "severe gastrointestinal pain." (Ex. 38, ¶¶ 34-35.) She recounted that K.J.D.'s condition further worsened over time, as he developed a progressively debilitating seizure disorder, which, tragically, has continued until the present day. (*Id*., ¶¶ 37-38, 49, 91.)

2. Brian Dempsey

Mr. Dempsey provided similar accounts of K.J.D.'s developmental status after his vaccinations of October 25, 1999. (1-Tr. 90-91.) He noted that about a week after K.J.D.'s vaccinations of October 25, 1999, K.J.D. was not responding to his name, to the point that he and Mrs. Dempsey suspected that K.J.D. was deaf. (1-Tr. 90-91; Ex. 39, ¶ 4.) Additionally, he also described K.J.D.'s "blank stares" at that time. (*Id*.)

In his affidavit, Mr. Dempsey asserted that the next time he went to see K.J.D.'s pediatrician, Dr. Smart (presumably on February 2, 2000, as reflected within K.J.D.'s medical records), "at this point [K.J.D.] was gone." (Ex. 39, ¶ 5.) Further, he averred that Dr. Smart acknowledged that K.J.D. "did change as a result of the vaccinations," and that Dr. Smart agreed to provide whatever assistance necessary to get K.J.D. the help he needed. (*Id*.) Mr. Dempsey again described this encounter with Dr. Smart at the "fact hearing." (1-Tr. 90-91.)

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[11] There were descriptions during the evidentiary hearing as to the definition of "absence seizures." Petitioners' expert Dr. Boles defined them as "staring episodes or staring spells***where you simply stare off into space for less than a second to several seconds. ***[Y]ou do not fall down, but your mind just simply goes blank for a while, and you cannot be easily distracted out of it." (2-Tr. 152-53.) Respondent's expert, Dr. Raymond, defined this phenomenon as being characterized as the "simultaneous onset of a generalized loss of consciousness associated with a characteristic EEG pattern." (2-Tr. 233-34.)

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

Petitioners and Respondent each presented expert reports and testimony from a single medical expert. At this point, I will briefly summarize both the qualifications and the opinions of these expert witnesses.

A. Petitioners' expert, Dr. Richard Boles

1. Qualifications

Richard Boles, M.D., earned his medical degree from the University of California, Los Angeles (UCLA) School of Medicine in 1987, subsequently completing his residency in pediatrics at the Harbor-UCLA Medical Center from 1988 to 1990. (Ex. 26, p. 1.) Thereafter, from July 1991 to November 1993, he completed a fellowship in genetics at the Yale University School of Medicine. (*Id*.; 2-Tr. 111-12.) He is board-certified in pediatrics, clinical genetics, and clinical biochemical genetics. (Ex. 26, pp. 1-2; 2-Tr. 112.)

Dr. Boles spent more than two decades at the University of Southern California's Keck School of Medicine, starting as an Assistant Professor of Clinical Pediatrics in 1993, and subsequently rising to the position of Associate Professor of Pediatrics -- a position he held until 2011. (Ex. 26, p. 2; 2-Tr. 114.) From 2012 to 2014, Dr. Boles served as a part-time Associate Professor of Clinical Pediatrics at that same institution, where he presently serves as a volunteer faculty member. (Ex. 26, p. 2.) Starting in 2012, he became affiliated with Courtagen Life Sciences, a genetic testing company, where he has served as a full-time Consultant and Medical Director since August 2014.[12] (Ex. 26, p. 4; 2-Tr. 114-15.) Since August of 2014, he has also concurrently maintained a private practice in Pasadena, California. (Ex. 26, p. 5.)

Dr. Boles lists numerous accomplishments within his *curriculum vitae*. He has published more than 70 articles in peer-reviewed journals, and has co-authored 69 abstracts. (Ex. 26, pp. 8-19.) Moreover, he has co-authored several book chapters, and has been invited to give more than 35 presentations within his medical specialty. (*Id.*, pp. 20-23.) Dr. Boles holds a patent for a method of detecting mitochondrial dysfunction. (*Id.*, p. 7.) He has served as a grant reviewer for several institutions, including the National Institutes of Health (NIH). (*Id.*, p. 4.) He has also served as an editor for scientific publications, such as *Mitochondrion* and *World Journal of*

[12] At the evidentiary hearing, Dr. Boles clarified his role as a medical advisor for Courtagen, and his involvement in the present case. (Tr. 227-28.) He testified that Dr. Goldstein (K.J.D.'s treating neurologist in Pittsburgh) contacted Dr. Boles, in his capacity as a medical advisor for Courtagen, to discuss K.J.D.'s genetic testing results from Courtagen. (*Id*.) After Dr. Boles' discussions with Dr. Goldstein about K.J.D., Petitioners' counsel contacted Dr. Boles to discuss the possibility of serving as a medical expert, resulting in his involvement with this case. (*Id*.)

Medical Genetics, additionally reviewing individual manuscripts for journals, such as *Neurology*, *Lancet*, and *Pediatrics*. (*Id.*)

Dr. Boles provided an expert report in this case on January 5, 2015 (Ex. 25), later providing a supplemental expert report on July 27, 2015 (Ex. 36). He also testified at the evidentiary hearing held in Washington, D.C. on January 14, 2016.

2. Summary of Dr. Boles' opinion

Dr. Boles' opinion was never clearly explained, but as I understand it, the gist of his opinion can be summarized as follows. Dr. Boles opined that, in an "abrupt" development after vaccinations were given to K.J.D. on October 25, 1999, K.J.D. suffered a "sudden and dramatic regression in behavior and developmental abilities." (Ex. 25, p. 3.) Specifically, he opined that one of those vaccinations, the MMR vaccination, caused K.J.D.'s "neurological deterioration," including his "developmental regression," "complex epilepsy," and "epileptic encephalopathy." (*Id.*, p. 6; 2-Tr. 160-62, 169.) Dr. Boles relied heavily on a perceived *close temporal relationship* between K.J.D.'s MMR vaccination and the onset of all of his neurological problems. He reasoned that "[s]ince all aspects of [K.J.D.'s] epilepsy and developmental regression started shortly following MMR vaccination, causality between [K.J.D.'s] disease and the vaccination is highly likely." (Ex. 25, p. 5, ¶ 4.) Although he acknowledged that K.J.D. has an autism spectrum disorder (ASD) (Ex. 25, p. 3; 2-Tr. 161), Dr. Boles stated that the ASD was only one of several brain disorders from which K.J.D. suffers, including "mental retardation," "epilepsy" (seizure disorder), and "cortical visual loss" (2-Tr. 161). Regarding K.J.D.'s epilepsy (seizure) diagnosis, Dr. Boles opined that the first seizures started "soon after" his vaccinations of October 25, 1999, when he had "episodes of staring in which he was non-responsive to loud noises." (Ex. 25, p. 3.)

As to *how* the MMR vaccine allegedly caused K.J.D.'s brain disorders, Dr. Boles' presentation was not clearly set forth, but he mentioned several possible factors. First, he pointed to the fact that K.J.D. has a variant in his CACNA1H (also known as "A1H") gene, a variant which allegedly gave him a "genetic predisposition toward vaccine-related neurological disease." (Ex. 25, pp. 4-7; 2-Tr. 120-27, 142-54, 164-68, 195-97.) Second, he relied on the possibility that K.J.D. suffers from "mitochondrial dysfunction," which dysfunction also, Dr. Boles suggested, made him more susceptible to injury by vaccination. (Ex. 25, p. 5, ¶¶ 2, 3, 7; Ex. 36, p. 3; 2-Tr. 127-28, 132, 186, 225.)

B. Respondent's expert, Dr. Gerald Raymond

1. Qualifications

Gerald Raymond, M.D., received his medical degree in 1984 from the University of Connecticut School of Medicine. (Ex. B, p. 2.)[13] From 1986 to 1989, he completed his residency in neurology at the Massachusetts General Hospital in Boston, Massachusetts. Thereafter, he completed two subsequent fellowships, one in developmental neuropathology (1989-1990) at the Universite Catholique de Louvain in Brussels, Belgium, and another in genetics and teratology (1990-1993) at the Massachusetts General Hospital. (*Id*.) He was board-certified by the American Board of Pediatrics until 2005. (*Id*., p. 14.) He is currently certified in Neurology with special competency in child neurology by the American Board of Psychiatry and Neurology, and in Clinical Genetics by the American Board of Medical Genetics. (*Id*.; 2-Tr. 230)

From 1993 to 2012, Dr. Raymond served as a pediatric neurologist for the Kennedy Krieger Institute, concurrently holding a faculty position at the Johns Hopkins University School of Medicine, where he rose to the position of Professor in Neurology. (Ex. B, p. 3.) Also during this time period, Dr. Raymond was a part of the medical staff within the Department of Pediatrics and Neurology at the Johns Hopkins Hospital. (*Id*.) Since December 2012, he has been a Professor in Neurology at the University of Minnesota School of Medicine, concurrently serving as a Director of Child Neurology at the University of Minnesota Medical Center and as an adjunct Professor of Neurology at Johns Hopkins School of Medicine. (Ex. A, p. 4; Ex. B, p. 3.)

Dr. Raymond's *curriculum vitae* shows numerous accomplishments. He has co-authored 96 peer-reviewed research articles, edited a book about one aspect of child neurology, and written 16 book chapters on genetics and neuroscience topics. (Ex. B, pp. 3-12.) Additionally, Dr. Raymond serves as a peer reviewer for journals such as the *American Journal of Medical Genetic*s and the *Journal of Neurology, Neurosurgery, and Psychology*. (*Id.*, p. 15.) Moreover, he has given numerous presentations throughout his career regarding his research in child neurology and genetics. (*Id.*, pp. 16-17.)

2. Summary of Dr. Raymond's opinion

Dr. Raymond agreed with Dr. Boles that K.J.D. has global developmental delay, an ASD diagnosis, and a seizure disorder. (Ex. A, p. 3.) However, he disagreed with Dr. Boles that K.J.D.'s condition was caused or aggravated by any of his vaccinations. (*Id.*, p. 6.) Dr. Raymond opined that there was "no evidence that K.J.D. had acute encephalopathy, seizure, or any other adverse event at the time of any of his immunizations." (Ex. A, p. 4.)

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[13] Exhibit B was filed without pagination; thus, for ease of reference, I will use the page numbers generated by the PDF filing. As such, the page entitled "Curriculum Vitae University of Minnesota School of Medicine" will be cited as "Ex. B, p. 2" with subsequent pages numbered accordingly.

Generally, Dr. Raymond testified that Dr. Boles' opinion was not supported by the contemporaneous medical records. Dr. Raymond strongly disagreed that K.J.D.'s *epilepsy* began soon after his October 1999 vaccinations, pointing out that K.J.D.'s medical records "do not even mention seizures until [K.J.D.] is over three years of age." (Ex. A, p. 4.) After reviewing video of K.J.D. taken soon after the October 1999 vaccinations, Dr. Raymond opined that these video clips were *not* reflective of K.J.D. having absence seizures. (2-Tr. 234.) In this regard, Dr. Raymond believed that if K.J.D. was in fact having absence seizures starting in 1999, then it would be "highly unlikely" that during the time period from late 1999 to June of 2003 (at which time K.J.D.'s medical records first reflect a seizure diagnosis), that those absence seizures would have gone unnoticed by all of his treating physicians. (2-Tr. 235.) Moreover, Dr. Raymond pointed to K.J.D.'s normal EEG test results in September of 2000 (Ex. 1, p. 52), which, he said argued against Dr. Boles' opinion that K.J.D.'s alleged staring episodes in late 1999 were the start of an absence epilepsy. (2-Tr. 234-35, 238.) In other words, Dr. Raymond opined that if K.J.D. was in fact suffering from absence epilepsy starting in November of 1999, then that seizure activity would have been reflected in the EEG testing conducted in September of 2000.

Dr. Raymond also testified that there is insufficient evidence in K.J.D.'s clinical or laboratory findings to support the diagnosis of a mitochondrial disorder, or any kind of improper function of his mitochondria. (2-Tr. 241, 255-56.) Further, he opined that there is "no evidence" either (1) that the A1H mutation is associated with exacerbation of a mitochondrial disease (2-Tr. 247), or (2) that the A1H mutation can be altered by vaccinations (2-Tr. 249).

Dr. Raymond further argued that K.J.D.'s medical records do not reflect him having any reactions to his MMR vaccination. (*E.g.*, 2-Tr. 252, 276-78.) He also testified that *even assuming* that K.J.D. has a channelopathy due to his A1H mutation *and* has a mitochondrial disorder, there still would not be a good reason to conclude that K.J.D.'s *MMR vaccination* of October 25, 1999, exacerbated that underlying mitochondrial disorder, or played any role in causing K.J.D.'s neurological injuries. (2-Tr. 252-53; Ex. A, p. 6.)

VI

SUMMARY OF MY DECISION

In this case, Petitioners seek a Program award, contending that K.J.D.'s neurological conditions were "caused-in-fact" by the MMR vaccination administered to him on October 25, 1999. After reviewing the record of this case, I have found Dr. Boles' view of the case to be quite unpersuasive, while Dr. Raymond's opinion was far more persuasive. There are several reasons to reject the Petitioners' theory that K.J.D.'s MMR vaccination caused his neurological deterioration.[14]

[14] Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

First and foremost, Dr. Boles based his opinion on two *clearly incorrect* assumptions about the facts of K.J.D.'s medical history -- namely that within weeks of his MMR vaccination of October 25, 1999, K.J.D. experienced (1) a "sudden" and "dramatic" regression in his developmental abilities; and (2) "absence seizures." For the reasons described below, I have determined that these factual assumptions are, much more likely than not, *incorrect*. (*See* Section VII of this Decision, below.)

Second, as a factual predicate, Dr. Boles' causation opinion was conditional upon K.J.D. suffering from "mitochondrial dysfunction." However, I find that there is no substantial evidence of mitochondrial dysfunction in the record. (*See* Section VIII(A)-(C) of this Decision, below.)

A third reason is that Dr. Boles provided no persuasive evidence for his opinions that either (1) mitochondrial dysfunction, or (2) the type of genetic variant which K.J.D. has, can make a child more susceptible to injury by MMR vaccination. (*See* Sections VIII(D) and IX of this Decision, below.)

A fourth reason is that a comparison of the expert reports and expert testimony in this case demonstrates that Respondent's expert was *far more persuasive* than Petitioners' expert. (*See* Sections VII through XI of this Decision, below.)

VII

PETITIONERS' EXPERT RELIED ON INCORRECT FACTUAL ASSUMPTIONS

The causation opinion of Petitioners' expert, Dr. Boles, was premised upon factual assumptions that run *contrary* to the clinical history presented by the medical records.

Specifically, Dr. Boles' causal theory is predicated upon two main factual assumptions: (1) that K.J.D. experienced an "abrupt," "sudden," and "dramatic" neurological deterioration, "shortly following" his MMR vaccination of October 25, 1999 (Ex. 25, pp. 3, 5); and (2) that K.J.D. also suffered the onset of "absence seizures" shortly after that MMR immunization (Ex. 25, p. 3, ¶ 4; Ex. 36, pp. 1-2.) These assumptions, however, are *not* supported by the factual record of this case. I address each of these assumptions below.

A. The overall record contradicts the assumption that K.J.D. suffered an abrupt, sudden, and dramatic neurological deterioration shortly after his October 1999 MMR vaccination.

First, Dr. Boles' theory was premised upon an assumption that K.J.D. manifested a sudden and dramatic neurological deterioration shortly after his MMR vaccination of October 25, 1999. (Ex. 25, pp. 3, 5.) My analysis of the overall record, however, leads me to conclude that this assumption was *not* accurate.

In this regard, Dr. Boles began his first report in this case by asserting that K.J.D.'s MMR vaccination of October 1999 was "accompanied by" an "abrupt deterioration," consisting of a "sudden and dramatic regression in his behavior and developmental abilities." (Ex. 25, p. 3, ¶ 2.)

Later in the same report, he clarified that because this sudden "developmental regression" occurred "shortly following MMR vaccination," that alleged temporal relationship allowed him to conclude that there was "causality" between K.J.D.'s neurological deterioration and the MMR vaccination. (Ex. 25, p. 5, ¶ 4.) But Dr. Boles failed to point to any *contemporaneous* medical records that supported this factual assumption; instead, he indicated that this assumption was based on the *parents' later testimony*. (*E.g.*, Ex. 36, p. 1; 2-Tr. 170.)

In this case, however, I do *not* find that it is more likely than not that K.J.D. experienced symptoms of a sudden and dramatic neurologic deterioration shortly following his MMR vaccination of October 25, 1999. Rather, I find that the medical records *contradict* Dr. Boles' assumption, and not even the parental testimony gives it significant support.

In this regard, I begin with the relevant caselaw, which states that medical records "warrant consideration as trustworthy evidence." *Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters usually accord more weight to the medical records. *See, e.g., Reusser v. HHS*, 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.").

To be sure, "it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." (*Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992)). However, in balancing these considerations, special masters in this Program have in most cases declined to credit later testimony over contemporaneous records. (*See, e.g., Stevens v. HHS*, No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990); *see also Vergara v. HHS*, No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.") *See also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").)

Here, K.J.D.'s medical records concerning the weeks after October 25, 1999, *do not* reflect K.J.D. having any kind of sudden or dramatic neurologic deterioration.

Four days after his vaccination, on October 29, 1999, K.J.D.'s parents called his pediatrician to report a concern that he had a "pink eye" infection. (Ex. 1, p. 7.) The next time the medical records reflect contact by K.J.D.'s parents with his physician is seventeen days later, on November 15, 1999. On that date, the medical records reflect a notation of a phone call from K.J.D.'s parents of "want[ing] to speak to Regina." (*Id*.) As discussed earlier, Mrs. Dempsey testified that "Regina" is an employee within the office of K.J.D.'s pediatrician who coordinated physician referrals. However, no description of *why* K.J.D.'s parents called on November 15 was recorded at that time.

One week later, on November 22, 1999, K.J.D. was examined by his pediatrician for red eyes and green drainage. (Ex. 34, p. 13.) At that visit, K.J.D. had a fever, was diagnosed with "Rom" (right otitis media, *i.e.*, ear infection), and was prescribed antibiotic medication. (*Id*.)

Mrs. Dempsey next called the pediatrician on November 26, 1999. At that time, Mrs. Dempsey wanted K.J.D.'s antibiotic medication changed because K.J.D. had a rash from his earlier-prescribed antibiotic medication. (Ex. 1, p. 7; 1-Tr. 32-33.)

Thereafter, approximately seven weeks after his vaccinations, K.J.D. had a follow-up visit with his pediatrician, to check his ear infection, on December 7, 1999. (Ex. 34, p. 12.) The notes from that visit reflect that K.J.D. was no longer pulling his ears, but was noted to have "green matter from nose [and] eyes," and that his rash had improved. (*Id*.)

In short, there are five medical record notations during the two-month period between the October 25 MMR vaccination and the end of 1999, yet none of them contain *any indication whatsoever* that K.J.D. had suffered a neurological deterioration of any kind, much less an "abrupt," "sudden," or "dramatic" one.

Then, more than ten weeks after his vaccinations, on January 8, 2000, K.J.D. was seen by a pediatrician with a chief complaint of "can't hear." (Ex. 34, p. 11.) This examining physician listed his ears as "perfect," but noted that K.J.D. had nose congestion, "URI" (upper respiratory infection), and hearing concerns. (*Id*.)

Next, at his fifteen-month well-child visit on February 2, 2000, his examining physician noted that K.J.D. "tunes things out" and "acts as if in another world." (Ex. 34, p. 19.) At that time, he was assessed with speech delay and was referred to an audiologist for further testing. (*Id*.)

The next day, on February 3, 2000, K.J.D. was seen by developmental specialists, where Mrs. Dempsey expressed "concerns related to autism," and reported that "she has an older son diagnosed with something in the autism spectrum." (Ex. 40, p. 6.) And K.J.D. underwent another assessment on February 22, 2000, where he was diagnosed as having developmental delay. (Ex. 40, p. 3.)

Accordingly, taken as a whole, the medical records of this case indicate that K.J.D.'s parents in fact did *not* report *any* signs of any neurologic deterioration, during several interactions with K.J.D.'s physicians in late October through early December of 1999. To be sure, the records do indicate that sometime between the visit of December 7, 1999, and the visit of January 8, 2000, K.J.D.'s parents *did* become worried about K.J.D.'s *hearing*. The records further show that by February of 2000, K.J.D.'s parents were concerned that he "tunes things out," and were suspicious of autism. But, the records show no signs whatsoever of a key fact that Dr. Boles assumed -- *i.e.*, an "abrupt," "sudden," and "dramatic" neurologic deterioration "shortly following" the MMR vaccination of October 25, 1999.[15]

[15] In this regard, I am mindful that a number of medical records, created months or years *after* the MMR vaccination in question, indicate that K.J.D.'s parents later reported that the onset

My conclusion in this regard, that Dr. Boles was *erroneous* in his assumption of an abrupt, sudden, and dramatic deterioration in K.J.D. shortly after his MMR vaccination, is *not* changed by my careful consideration of the affidavits and hearing testimony of K.J.D.'s parents.

I note first that even the parental testimony during this litigation does not actually describe an "abrupt," "sudden," or "dramatic" neurological deterioration in K.J.D., either shortly after the MMR vaccination or at any time. In the affidavit of K.J.D.'s mother, for example, she stated that K.J.D.'s "medical problems began to happen" *over a period of more than three months*, between October 25, 1999, and February 2, 2000. (Ex. 38, p. 5, ¶ 14.)

To be sure, K.J.D.'s mother testified at the first evidentiary hearing that she began to notice an apparent hearing loss[16] in K.J.D., which caused K.J.D.'s parents to call the pediatrician's office on November 15, 1999. (1-Tr. 25-26.) K.J.D.'s father testified at the hearing that he noticed that apparent hearing problem "about a week" after the October 25 immunizations. (1-Tr. 90.) However, while I do *not* find that K.J.D.'s parents were intentionally untruthful, [17] I could *not* credit their testimony that K.J.D.'s apparent hearing loss in fact began between October 25 and November 15, 1999. Rather, based on the medical records, the parents' concern on this point seems to have occurred shortly before the pediatrician visit of January 8, 2000. That is because *no hearing concerns* were reported during the physician visits on November 22 and December 7, 1999, but were first reported at the visit of January 8, 2000. (Ex. 34, pp. 11, 12, 13.) Further, *none* of the parents' three *affidavits* mentions an apparent hearing loss in the period between October 25 and November 15, 1999. (*See* Exs. 23, 38, and 39.)

Accordingly, for the reasons set forth above, I conclude as a matter of fact that Dr. Boles was *mistaken* when he based his opinion on the assumption that K.J.D. experienced an "abrupt,"

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of certain symptoms in K.J.D. occurred "following his MMR vaccination." (Ex. 43, p. 1; *see also e.g.*, Ex. 3, p. 5; Ex. 4, p. 3; Ex. 44, p. 1; Ex. 46, p. 1; Ex. 48, p. 1; and other medical records contained at Exs. 43-49, all created on or after May 30, 2000.) But those later records do not indicate *how soon* after the MMR vaccination the described symptoms occurred. More importantly, I rely more heavily on the medical records created in *late 1999 and early 2000*, as detailed above, rather than records created long afterwards.

[16] I refer to an "apparent" hearing loss, because the records and expert testimony make it appear likely that when K.J.D.'s parents did find that he was not responding to sounds (probably in December of 1999 -- see p. 11 above), this phenomenon was not a *hearing* problem at all, but likely a symptom of *autism*. (*E.g.*, 2-Tr. 237-38.)

[17] I stress that I am not questioning the *sincerity* or *truthfulness* of Mr. and Mrs. Dempsey. I have no reason to doubt that they believe their recollections to be accurate, and that they are sincere in their belief that K.J.D. experienced a severe reaction to his vaccinations within a few weeks of his October 25 vaccinations. I simply find that their testimony, presented 14 years after the fact, does not have sufficient indicia of reliability to be trusted over the *contemporaneous medical records*, which constitute a conflicting, contemporaneously-recorded, recitation of the facts.

"sudden," and "dramatic" neurologic deterioration "shortly following" the MMR vaccination of October 25, 1999.

B. The overall record also contradicts the assumption that K.J.D. suffered "absence seizures" soon after his October 1999 MMR vaccination.

Dr. Boles also erred in a *second* key factual assumption -- that K.J.D. suffered "absence seizures" within weeks of his October 1999 MMR vaccination. (Ex. 25, p. 3, ¶ 4; Ex. 36, pp. 1-2.) This second factual assumption of Dr. Boles is, again, *not* borne out by a full examination of the record in this case.

To be sure, Dr. Boles explicitly acknowledged the complete lack of any medical records from K.J.D.'s early life regarding K.J.D.'s alleged staring episodes, which Dr. Boles believes were "absence seizures." (Ex. 36, pp. 1-2.) Instead, Dr. Boles once again relied primarily on the *parents' assertions* in order to conclude that K.J.D. had absence seizures soon after his MMR vaccination. (*Id*.)

1. "Absence seizures" described

The record in this case contains two different descriptions of "absence seizures" by the two parties' experts. Petitioners' expert, Dr. Boles, defined them as "staring episodes or staring spells***where you simply stare off into space for less than a second to several seconds. ***[Y]ou do not fall down, but your mind just simply goes blank for a while, and you cannot be easily distracted out of it." (2-Tr. 152-53.) Respondent's expert, Dr. Raymond, defined this phenomenon as being characterized by the "onset of a generalized loss of consciousness associated with a characteristic EEG pattern." (2-Tr. 233-34.) Thus, "absence seizures" involve instances in which a person seems to "go blank," for a short period of time, becoming oblivious to his or her surroundings. (The main difference between the two experts seems to be that, according to Dr. Raymond, one cannot *confirm* that such a clinical episode constitutes an "absence seizure" without a finding of a characteristic EEG pattern when the person is tested during such an episode.)

In this case, Dr. Boles appears to rely on accounts by K.J.D.'s parents stating that between October 25, 1999, and February 2, 2000, K.J.D. had "staring episodes" in which he would "stare off into space." (Ex. 38, p. 5, ¶ 15; Ex. 39, p. 2, ¶ 4; 1-Tr. 90.) Dr. Boles infers that such episodes constituted absence seizures. (Ex. 25, p. 3, ¶ 4; Ex. 36, pp. 1-2.)

2. K.J.D.'s medical records contradict the theory that he experienced absence seizures soon after his MMR vaccination of October 1999.

After a close examination of K.J.D.'s medical records from the time period after his MMR vaccination of October 1999, I am persuaded that those medical records *contradict* Dr. Boles' theory that K.J.D. had absence seizures in the weeks following his MMR vaccination of October 25, 1999.

First, K.J.D.'s medical records made in late 1999 and early 2000 make *no mention whatsoever* of blank stares or staring episodes. See notes of pediatric visits on November 22, 1999 (Ex. 34, p. 13); December 7, 1999 (*id*., p. 12); and February 2, 2000 (*id*., p. 11). That is

true even though these records report many common, minor health symptoms such as "red eyes" and "green drainage" (*id*., p. 13), rash and pulling at ears (*id*., p. 12), and nose congestion (*id*., p. 11).

In this regard, I did listen carefully to the parental testimony alleging the occurrences of "staring" episodes and "staring into space" by K.J.D. in late 1999. (Ex. 38, p. 5, ¶ 15; Ex. 39, p. 2, ¶ 4; 1-Tr. 90.) However, I could not accept this testimony as accurate. In my view, if K.J.D. had actually experienced significant staring episodes that might have been absence seizures starting in late 1999, as later alleged by his parents, K.J.D.'s parents would have reported such episodes to his treating physicians at the time, who would have recorded such reports in his medical records. Thus, because I decline to credit Petitioners' testimony with regard to K.J.D.'s alleged staring episodes in the weeks after his October 25 vaccination, I likewise decline to accept Dr. Boles' opinion about "absence seizures" based upon on that testimony.

Second, as pointed out by Dr. Raymond, while K.J.D. was 12 months old in October of 1999, K.J.D.'s medical records in fact make *no mention* of K.J.D. having seizures of any type until he was "over three years of age." (Ex. A, p. 4.) For example, see K.J.D.'s neurology consult on January 18, 2001. (Ex. 1, p. 45.) At that time, his treating neurologist assessed K.J.D. with having "autistic features including repetitive activity, language delay and impairment of social interaction." (*Id.*) Although this neurologist observed the range of developmental abnormalities in K.J.D. at that time, this neurologist *did not mention seizures*. Similarly, on April 30, 2001, K.J.D. was once again evaluated for developmental delay. (Ex. 4, pp. 4-5.) Although the examining physician noted that the behavioral profile of K.J.D. was "consistent with a diagnosis of pervasive developmental disorder, autism," there were no notations of *seizure activity* at that time. (*Id.*, p. 5.) I also note that one of K.J.D.'s treating neurologists from Pittsburgh, after taking a history of K.J.D.'s neurological symptoms on September 13, 2004, reported in her neurology evaluation that K.J.D.:

> was *initially* diagnosed with seizures in June 2003, when he presented with a prolonged episode of, what appears to be, a complex partial seizure with secondary generalization and actually required ICU admission for status epilepticus.

(Ex. 37, pp. 9-10, emphasis added.) Thus, this notation of one of K.J.D.'s own treating neurologists further contradicts Dr. Boles' factual assumption regarding the onset of K.J.D.'s seizure history.

Third, Dr. Raymond also highlighted K.J.D.'s normal EEG of September 1, 2000, which showed no signs of seizure activity by K.J.D. (2-Tr. 234-35; Ex. 1, p. 52.) Dr. Raymond deemed this normal EEG result to mean that it would be "*extraordinarily unlikely*" that K.J.D. could have had "an early-onset absence with a normal EEG." (2-Tr. 234, emphasis added.) Dr. Boles did not refute this testimony of Dr. Raymond.

Moreover, I am further persuaded by Dr. Raymond's explanation as to the clinical reasons why the occurrence of absence seizures would be highly unlikely in K.J.D. at around one year of age. Dr. Raymond testified that absence epilepsy usually does not begin until at least three to four years of age, thus indicating that the alleged onset of such seizures in K.J.D. at approximately one year of age would be highly unlikely. (2-Tr. 234.) Further, Dr. Raymond pointed out that even *Petitioners' own reports* of K.J.D.'s symptomatology after his vaccinations

of October 1999 -- *i.e.*, instances of K.J.D. staring off in space, tuning his parents out, and generally acting as if he was in his own world -- are, in fact, *consistent* with the onset of an *ASD*, and thus need not be construed as evidence of absence seizures. (2-Tr. 237-38.) Again, Dr. Boles did not refute those arguments of Dr. Raymond.[18]

3. The video of an alleged absence seizure.

Additionally, with respect to the issue of "absence seizures," I note that Petitioners presented *video* of K.J.D. in 1999. They pointed to a particular video segment recorded on November 18, 1999, and argued that this was an example of an absence seizure by K.J.D. K.J.D.'s mother expressed the opinion that this incident represented an "absence seizure." (Ex. 38, pp. 5-6; 1-Tr. 80-81.)

Petitioners, however, later presented a video segment to Dr. Boles -- apparently the same segment identified by the mother as an absence seizure -- and Dr. Boles could say only that the episode "may or may not be a staring spell." (2-Tr. 181.) Then Dr. Raymond, after viewing the same video segment shown to Dr. Boles (2-Tr. 234), stated that "I just don't think clinically, in my judgment, that was characteristic of an absence seizure" (*id.*).

Therefore, the video certainly did *not* persuade me that K.J.D. suffered an absence seizure on November 18, 1999, or anytime in 1999. Mrs. Dempsey, though clearly a loving mother, is not a medical doctor, much less a neurologist, so that her opinion that the November

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[18] Additional support for crediting Dr. Raymond's view concerning whether K.J.D. had absence seizures is found in the medical definition of absence seizures. Dorland's Illustrated Medical Dictionary defines "absence seizure" as:

> [T]he seizure seen in absence epilepsy, consisting of a sudden momentary break in consciousness of thought or activity, sometimes accompanied by automatisms or clonic movements, especially of the eyelids. On the electroencephalogram it is characterized by a specific symmetrical spike and wave type occurring at three cycles per second.

(DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012), p. 1688.) Comparing the testimony explaining absence seizures from both experts, I find Dr. Raymond's definition and explanation of absence seizures to be more complete, and more in keeping with the above-cited medical definition of this phenomenon. A further support for my reliance on Dr. Raymond's explanation is that one item of medical literature submitted by *Dr. Boles* in this case supports Dr. Raymond's definition. The Chen article (Ex. 31) defines absence seizures as follows:

> Absence seizures are brief, generalized epileptic seizures of sudden onset and termination. Impairment of consciousness and generalized spike-and-slow wave discharges (SWD) on EEG are two essential features of absence seizure.

(Ex. 31, p. 1.) In contrast, Dr. Boles' explanation of "absence seizures" was incomplete at the very least, and seemed to be limited in its definitional scope to suit his own causation theory in this case. (2-Tr. 152-53.)

18 video segment shows an "absence seizure" is of very slight evidentiary value. Meanwhile, even Petitioners' *own expert* could not say whether the episode constituted an absence seizure, while Respondent's expert opined that it was *not* an absence seizure. (2-Tr. 234, 276.)

4. Dr. Amy Goldstein

I also note that Dr. Amy Goldstein, another of K.J.D.'s treating neurologists in Pittsburgh, made the following notation during a neurology evaluation of July 9, 2015:

> Parents brought in videos of [K.J.D.] at age 1, shortly after he began to walk. He had a few suspcious [*sic*] episodes while walking consisting of behavioral arrest (stopped walking), lost focus and had stumbling. These events are suspuicious [*sic*] for brief seizure.

(Ex. 37, p. 13.) She made a similar statement in the notes of another neurology evaluation of September 3, 2015. (*Id.*, p. 18.) Thus, I acknowledge that one of K.J.D.'s treating neurologists was *suspicious* of K.J.D. having seizures years before, after viewing videos brought in by K.J.D.'s parents during his neurology consult. However, Dr. Goldstein did *not* actually opine that what she saw on the video was in fact K.J.D. *actually having* seizures. Moreover, Dr. Goldstein did not submit an affidavit in this case, or testify at the evidentiary hearing held in this case. Therefore, while I do take into account Dr. Goldstein's suspicions, without more explanation as to what her exact beliefs were concerning the video footage of K.J.D. (or, for that matter, which *specific* video footage of K.J.D. she observed), I cannot give this brief suggestion significant weight, especially when compared with Dr. Raymond's opinion on this issue. Thus, I am still more persuaded by Dr. Raymond's testimony on this issue.

5. Summary concerning absence seizures

In short, I conclude, based upon the entire record, that Dr. Boles again based his opinion on a false factual assumption, when he assumed that K.J.D. experienced the onset of absence seizures shortly after his MMR vaccination of October 25, 1999.

C. Dr. Boles' contradictory testimony towards the end of the hearing concerning absence seizures.

Throughout all of his expert reports and virtually all of his hearing testimony, Dr. Boles seemed to have based his causation opinion, in significant part, on the assumption that K.J.D.'s absence seizures started *soon after* his MMR vaccination of October 25, 1999. As noted in the section above, I find that to have been a misassumption of fact, and thus a fatal flaw in his opinion. However, at the very end of the evidentiary hearing, Dr. Boles appeared to contradict himself, in an answer to a question asked by Respondent's counsel on cross-examination. That testimony was as follows.

> **Q:** Is your opinion that -- I'll call it a vaccine reaction -- dependent on a finding that the beginning of his epilepsy started, let's just say, within a -- within four months of vaccination?

> **A:** No, it's not dependent on that, because, I mean, in patients with epileptic encephalopathy, sometime epilepsy doesn't show up until school years or even in adolescence, but the encephalopathy was there before. So, no, it's -- it's not dependent. Epilepsy could come up years later.

(2-Tr. 289.) Thus, by answering the above question in that way, he seemed to *contradict* what theretofore had appeared to be a *significant part* of his causation theory -- the assertion that the alleged onset of K.J.D.'s absence seizures within weeks of his MMR vaccination of October 25, 1999, was evidence that K.J.D.'s neurological deterioration was *caused by* that MMR vaccination. (For example, in summarizing his opinion of K.J.D.'s case, Dr. Boles stated that "[s]ince all aspects of [K.J.D.'s] epilepsy and developmental regression started shortly following MMR vaccination, causality between [K.J.D.'s] disease and the vaccination is highly likely." (Ex. 25, p. 5.)) Through the above-quoted question and answer at the hearing, Dr. Boles seemed to make a significant shift in his expert opinion, subtracting that alleged temporal relationship (between the MMR vaccination and the onset of absence seizures) as a pillar of his causation opinion.

This apparent abrupt change in Dr. Boles' causation reasoning, in my view, weakened even further the credibility of his overall causation opinion. If, as Dr. Boles had earlier testified, K.J.D. did suddenly experience the onset of his seizure disorder within weeks of his MMR vaccination, that temporal relationship would seem to be at least some circumstantial evidence (though still weak evidence) supporting Dr. Boles' view that the MMR vaccine caused K.J.D.'s seizure disorder and his other neurological problems. Dr. Boles' willingness to suddenly, with virtually no explanation, state that his opinion would be the same *without* that alleged temporal relationship, made me question whether *any* assumption of fact would change Dr. Boles' opinion that the MMR vaccine harmed K.J.D.'s brain. This, in my view, made Dr. Boles appear to be an inconsistent witness.

D. Summary: Dr. Boles' incorrect assumptions regarding the alleged existence of a sudden and dramatic reaction by K.J.D. to his MMR vaccination, and regarding the onset of his absence seizures, are fatal to his causation opinion.

In sum, the most obvious reason to reject Dr. Boles' and Petitioners' causation claim in this case is that Dr. Boles based his causation theory on two distinctly flawed assumptions. First, he mistakenly assumed that K.J.D. experienced a "sudden" and "dramatic" reaction to his MMR vaccination in question, within weeks of his vaccination, when in fact the record indicates that that did *not* happen. Second, Dr. Boles also, throughout the course of his expert report and virtually all his hearing testimony, based his opinion on the assumption that K.J.D. suffered absence seizures within a few weeks of his MMR vaccination in question. For the reasons discussed above, I also conclude that this assumption was also factually incorrect.

Therefore, because Dr. Boles, Petitioners' sole expert witness, based his causation opinion on two clearly flawed factual assumptions, I could end my analysis at this point -- Petitioners have clearly failed to prove their causation case via Dr. Boles' flawed testimony.[19]

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[19] "[T]o the extent that it relies on the testimony of the petitioners' witnesses as to the occurrence and timing of events, [expert medical opinion] must stand or fall with the fact testimony." (*Murphy v. HHS*, 90-882V, 1991 WL 74931, at *3 (Fed. Cl. Spec. Mstr. April 25,

However, in the interest of completeness, in the pages to follow I will explain several other reasons for rejecting Petitioners' causation claim in this case.

VIII

DR. BOLES' TESTIMONY CONCERNING POSSIBLE "MITOCHONDRIAL DYSFUNCTION" DID NOT SUPPORT PETITIONERS' CAUSATION CLAIM

A. Introduction

Most cells in the human body contain "mitochondria," which supply energy to the cell.[20] Dr. Boles indicated at different times that K.J.D. has a "mitochondrial dysfunction," "mitochondrial disorder," or "mitochondrial disease." (*E.g.*, Ex. 25, p. 5, ¶ 2; Ex. 36, p. 3, ¶ 1; 2-Tr. 127-28, 132, 186.) He also suggested, with scant explanation, that the existence of mitochondrial dysfunction in K.J.D. somehow made him more susceptible to being injured by vaccinations. (*See* Ex. 25, p. 5, ¶¶ 3,7; Ex. 36, p. 3; 2-Tr. 225.)

However, after studying the entire record of this case, I conclude that (1) Petitioners have failed to show that it is "more probable than not" that K.J.D. has mitochondrial dysfunction, disorder, or disease; and (2) that even if one assumes that K.J.D. *does* have mitochondrial dysfunction, that fact would *not* offer *any* significant support to Petitioners' contention that the *MMR vaccination* contributed to causing any of his tragic conditions.

B. Dr. Boles was inconsistent in stating whether K.J.D. has mitochondrial "dysfunction," a mitochondrial "disorder," or a mitochondrial "disease."

Dr. Boles was inconsistent in stating whether K.J.D. suffers from mitochondrial "dysfunction," mitochondrial "disorder," or a mitochondrial "disease." For example, in his very first mention of the mitochondrial issue, Dr. Boles both used the terms "mitochondrial *disease*" in discussing K.J.D.'s case, and then opined explicitly that he had a "probable mitochondrial *disorder*." (Ex. 25, p. 5, ¶ 2, emphasis added.) In his second written report, Dr. Boles again used the term mitochondrial "*disease*" in reference to K.J.D., while adding the term mitochondrial "*dysfunction*." (Ex. 36, p. 3, ¶ 1, emphasis added.) In his hearing testimony, on direct examination, Dr. Boles opined that based upon K.J.D.'s history, his condition is "extremely highly likely to be a mitochondrial *disorder*." (2-Tr. 132.)

Under cross-examination, however, Dr. Boles backed away from the term "mitochondrial disorder," stating that "I did not make a diagnosis of mitochondrial *disorder*," but alleged only "mitochondrial *dysfunction*." (2-Tr. 208, emphasis added.) Later, he similarly backed away from the term "mitochondrial *disease*," stating that "I have never said K.J.D. had a mitochondrial

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1991), *aff'd,* 23 Cl. Ct. 726 (1991), *aff'd,* 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992).) Thus, because I decline to credit Petitioners' testimony with regard to K.J.D's alleged severe reaction to his October 25 vaccinations, and to alleged absence seizures in 1999, I likewise decline to accept Dr. Boles' opinion based upon on that testimony.

[20] DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012), p. 1169.

disease" (2-Tr. 280, emphasis added), again seeming to now opine only that K.J.D. had mitochondrial *dysfunction*.

Dr. Boles defined "mitochondrial dysfunction" as "when the mitochondria of the cells are not functioning correctly." (2-Tr. 118.) At one point he attempted, quite unclearly, to make a distinction between mitochondrial "dysfunction" and mitochondrial "disease," but admitted that the term "mitochondrial disease" is "used pretty loosely" in general. (2-Tr. 118-19.)

In any event, Dr. Boles, as noted above, eventually clarified that he is alleging that K.J.D. suffered from mitochondrial "dysfunction." Accordingly, though the distinction among the terms is less than clear, in this discussion I will use the term "mitochondrial dysfunction," and I will decide whether Petitioners have shown that K.J.D. had "mitochondrial dysfunction."

C. Petitioners have not shown that K.J.D. has mitochondrial dysfunction.

Petitioners and Dr. Boles have failed to show that it is "more probable than not" that K.J.D. has "mitochondrial dysfunction," for the reasons stated below.

1. Dr. Boles' questionable support for diagnosing mitochondrial dysfunction

a. Clinical picture

Dr. Boles pointed to K.J.D.'s clinical features and laboratory findings, as support for his theory that K.J.D. has mitochondrial dysfunction. Commenting on clinical symptoms, Dr. Boles opined that K.J.D. had numerous symptoms that were allegedly reflective of mitochondrial dysfunction -- his developmental regression, epilepsy, gastrointestinal issues, muscle abnormalities, and immune abnormalities. He testified that K.J.D.'s symptoms of mitochondrial dysfunction included, among other things, developmental delay, epilepsy, severe intellectual disability, cortical visual loss, and precocious puberty. (2-Tr. 130-31.) Moreover, Dr. Boles listed K.J.D.'s gastrointestinal symptoms to include colitis, irritable bowel syndrome, constipation, and gastroesophageal reflux; his muscle abnormalities to include myopathy, hypotonia, and skeletal muscle weakness; and his immune abnormalities to include susceptibility to viral infections. (*Id*.)

Dr. Raymond, however, strongly argued against this list of K.J.D.'s symptomatology provided by Dr. Boles, asserting instead that K.J.D.'s *primary* medical records show "very little evidence" of these symptoms. (2-Tr. 238-39.) Dr. Raymond elaborated on K.J.D.'s "primary medical records," drawing a distinction between K.J.D.'s traditional medical care providers and his care under non-traditional "alternative" medical providers. Thus, he described some of the symptoms upon which Dr. Boles relied as being "classic listing [of symptoms] that is often entered into *** by practitioners of alternative methods in the autism world." (2-Tr. 239.) In other words, Dr. Raymond was doubtful of some of the symptoms described by K.J.D.'s "alternative" medical care providers.[21] (And I found this concern of Dr. Raymond to be credible,

[21] Dr. Raymond described "alternative practitioners" who use unproven medical treatments upon autistic patients. (2-Tr. 282-83.) And I note, as an example, that many of K.J.D.'s medical records from the Watson Institute described K.J.D.'s participation in a study by "Dr. Geier" of Maryland, one such "alternative practitioner" who has unsuccessfully urged that vaccines can

having myself heard very dubious testimony in many cases from such "alternative providers," who seem to have an unswerving belief that *vaccines can cause autism*, and thus seem to find symptoms that supposedly support their causation theories, even when other, "mainstream" medical doctors fail to report such symptoms in the same individuals.)

Regardless of the validity of K.J.D.'s alleged symptomatology upon which Dr. Boles relied, another persuasive point advanced by Dr. Raymond was his argument against making a *solely clinical* diagnosis of a mitochondrial disorder. In this regard, Dr. Raymond believed that the scope of symptomatology in patients with mitochondrial disorders "covers a variety of things," including numerous nonspecific symptoms. (2-Tr. 239.) Thus, he noted that making a clinical diagnosis, without a "clear primary evidence of an alteration in either a nuclear or mitochondrial DNA," to be inherently imprecise. (2-Tr. 240.) This point is crucial, since K.J.D.'s medical records do not indicate that K.J.D.'s genetic test results were reflective of a mitochondrial disorder. Hence, *even assuming* that K.J.D. did display all of the symptomatology upon which Dr. Boles relied, I agree with Dr. Raymond that those symptoms would *still reflect non-specific symptoms*, which, neither individually nor collectively, warrant a diagnosis of a mitochondrial disorder.

Moreover, Dr. Raymond also noted that, upon his examination of K.J.D.'s medical records, he saw no evidence indicating that either Dr. Boles or K.J.D.'s treating neurologist, Dr. Goldstein, applied the sets of criteria generally accepted within the medical community in diagnosing mitochondrial disorders, in order to appropriately diagnose K.J.D. with such a disorder. (2-Tr. 278.)

b. Dr. Boles' allegations concerning a brain MRI of April 2003

During the evidentiary hearing, Dr. Boles referred to a brain MRI of K.J.D. alleged to have been conducted in April of 2003. (2-Tr. 139-41.) He alleged that this brain MRI showed "punctate lesions" (small spots within the brain) (2-Tr. 139), opining that these lesions are "often what we see in patients with mitochondrial dysfunction/mitochondrial disease." (2-Tr. 141.) Dr. Boles elaborated that this brain MRI showed small spots within the brain reflecting "apoptosis" (cell death) within K.J.D.'s brain -- evidence that he believed was indicative of a mitochondrial disorder. (2-Tr. 138-41.)[22]

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cause autism, and has used unproven methods to treat autism. In a prior case before me, *Hooker v. HHS*, No. 02-472V, 2016 WL 3456435 (Fed. Cl. Spec. Mstr. May 19, 2016), Respondent supplied evidence which showed that the medical license of Dr. Mark Geier has been revoked by the Maryland State Board of Physicians ("Board"). 2016 WL 3456435, at *6. In revoking Dr. Geier's medical license, the Board concluded that Dr. Geier had displayed "an almost total disregard of basic medical and ethical standards," and "exploited these [autistic] patients under the guise of providing competent medical treatment." 2016 WL 3456435, at *31.

[22] At this point in the hearing, Respondent's counsel objected that no report describing this alleged brain MRI, in April of 2003, was within the submitted medical records in this case. (2-Tr. 138-39.) Respondent's counsel acknowledged that that MRI report was "referred to in the records," but stated that he did not see the actual MRI report within the medical records

However, Dr. Raymond asserted that *even assuming* that K.J.D.'s medical records included an MRI from April of 2003, based on *Dr. Boles' own* written description of the MRI report in Dr. Boles' expert report, he would still disagree with Dr. Boles' *interpretation* of that MRI. (2-Tr. 250-51.) In this regard, Dr. Raymond explained why that description did not sound to him like cellular death in the brain, as Dr. Boles testified. (*Id.*) In other words, based upon the written description of the alleged brain MRI of April of 2003, contained in *Dr. Boles' own written report* at the time he reviewed the MRI report, Dr. Raymond still would be unpersuaded that this MRI evidence would change his overall opinion as to K.J.D. having mitochondrial dysfunction/disorder. (*Id.*)

After a review of the record submitted in this case, I could not find a report of this MRI in the medical records. However, even based upon Dr. Boles' own written description of the MRI report, I still am not persuaded that that MRI evidence indicates that K.J.D. has mitochondrial dysfunction. Rather, I am more persuaded by Dr. Raymond's explanation of this evidence above. Hence, this MRI from April of 2003 would not change my ultimate finding that Dr. Boles was not persuasive, to a standard of "more probable than not," that K.J.D. suffers from mitochondrial dysfunction.

c. Laboratory findings

Dr. Boles highlighted several of K.J.D.'s laboratory findings to support his opinion that K.J.D. had mitochondrial dysfunction -- his low level of carnitine (a compound important in detoxifying mitochondria) (2-Tr. 132-33); elevated urine lactate and pyruvate levels (signifying the abnormal situation when the cell's energy demands exceed the energy supply) (2-Tr. 134); elevated markers for ethylmalonic compound (a compound important in the metabolism of protein and fats) (2-Tr. 134-35); and elevated "Krebs cycle intermediates" (signifying that there are abnormalities in the metabolism of fats and proteins) (2-Tr. 137; Ex. 25, p. 3).[23] Dr. Boles opined that these laboratory findings collectively were reflective of abnormalities within K.J.D.'s mitochondria. However, Dr. Raymond pointed out that the laboratory testing results that Dr. Boles referenced were taken at a time when K.J.D. was already under the care of "alternative

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submitted in this case. (*Id.*) In contrast, Dr. Boles asserted that this MRI report was within the records provided to him. (*Id.*) Upon my admonition of Petitioners' counsel for referring to this MRI report in his direct examination, yet not being prepared to cite to the specific record when asked, Petitioners' counsel sought to find this specific cite. (*Id.*) By the end of the evidentiary hearing, however, Petitioners' counsel was not able to provide a specific citation to this record. I have not found it in the submitted records. Thus I can only surmise that this MRI report likely has not been submitted by Petitioners in this case.

[23] Dr. Boles also claimed that K.J.D. had a low serum creatine level. (Ex. 25, pp. 3-4.) However, when asked on cross-examination to cite where in K.J.D.'s medical records his low serum creatine level was listed, Dr. Boles was not able to do so. (2-Tr. 205-06.)

practitioners," and when he was following special dietary regimens.[24] (2-Tr. 240.) Thus, Dr. Raymond suggested, these abnormal laboratory test results were due to K.J.D.'s ongoing care from alternative medical providers, and not supportive of mitochondrial dysfunction diagnosis. (*Id*.) (And Dr. Boles acknowledged that a restricted diet *could* explain some of the lab findings upon which Dr. Boles relied. (2-Tr. 207.))

As further evidence to support his analysis, Dr. Raymond pointed to K.J.D.'s earlier laboratory testing results (May 15, 2001 -- see Ex. 1, p. 43) *prior* to the time when K.J.D. came under the care of alternative practitioners. (2-Tr. 240.) These laboratory testing results showed K.J.D. having *normal* organic acid levels, which Dr. Raymond deemed weighed against the proposition that K.J.D.'s later abnormal laboratory results were truly suggestive of a diagnosis of a mitochondrial disorder. (2-Tr. 240; Ex. 1, p. 43.) Moreover, Dr. Raymond discounted other laboratory testing abnormalities (such as K.J.D.'s low serum creatinine levels that were highlighted by Dr. Boles), opining that these low levels were not indicative of a *specific* finding for mitochondrial disease. (2-Tr. 241; Ex. 25, pp. 3-4.)

Moreover, Dr. Raymond noted that testing specifically looked for abnormalities in K.J.D.'s mitochondrial DNA, and found none. (2-Tr. 253.)

2. I am persuaded by Dr. Raymond's view that K.J.D. did not have mitochondrial dysfunction.

Based on his review of K.J.D.'s medical records, Dr. Raymond's assessment was that K.J.D. did *not* have a mitochondrial disorder/dysfunction. (Ex. A, p. 5; 2-Tr. 241.) I have already set forth above some of Dr. Raymond's reasoning for that conclusion.

Further, Dr. Raymond argued that *if* K.J.D. was undergoing a "mitochondrial encephalopathy" (*i.e.*, brain damage due to a mitochondrial disorder) soon after his MMR vaccination in question, his symptomatology would actually be *more severe* than what is reflected in his medical records. (2-Tr. 244.) Specifically, K.J.D.'s medical records in the time period soon after his vaccinations of October 1999 showed no changes in gross motor and fine motor developmental parameters -- developmental parameters which, Dr. Raymond believed, would have certainly changed if K.J.D. was indeed undergoing mitochondrial encephalopathy. (*Id*.) Dr. Boles did not present any rebuttal to his point, leaving Dr. Raymond's testimony on this issue completely unchallenged.

I also note that one of K.J.D.'s treating pediatric neurologists, Dr. Shelly Williams, treating K.J.D. in 2004, did not even see a need for a mitochondrial disease work-up at that time. (See Ex. 37, pp. 9-12; see also 2-Tr. 199.) And Dr. Boles also acknowledged that when the above-discussed Dr. Goldstein ordered a test relating to possible mitochondrial dysfunction (a "nuclear gene panel"), that test result was *negative*. (2-Tr. 201-02.)

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[24] In the notes of a neurology evaluation on September 13, 2004, one of K.J.D.'s treating neurologists, Dr. Shelley Williams, recorded that K.J.D. "is on a restricted gluten-free diet and dairy free diet." (Ex. 37, p. 11.)

After considering Dr. Raymond's criticisms of Dr. Boles' claimed mitochondrial disorder diagnosis, and examining Dr. Boles' very general rebuttal statements that did not provide any specific commentary as to how Dr. Boles' clinical experience applied to rebut Dr. Raymond's opinions as to K.J.D.'s clinical picture, I am persuaded by Dr. Raymond's opinion on this issue. Under these circumstances, Dr. Boles' opinion of a mitochondrial dysfunction diagnosis simply cannot be credited.

3. Dr. Boles' claim that one of K.J.D.'s treating physicians opined that K.J.D. had mitochondrial disorder/dysfunction

One physician who treated K.J.D. during the years 2013-2015 was Dr. Amy Goldstein, a neurologist. (*See generally* Exs. 24 and 37.) Dr. Boles stated that Dr. Goldstein's assessment of K.J.D.'s mitochondrial disorder diagnosis was "essentially the same" as his own. (Ex. 25, p. 5, ¶ 2; 2-Tr. 186.) He further represented at the evidentiary hearing that he spoke with Dr. Goldstein about K.J.D.'s condition by telephone, and that she was in agreement that mitochondrial disorder is "the most likely diagnosis in this patient." (2-Tr. 186, 200.) However, the medical records from Dr. Goldstein's treatment of K.J.D. *do not* corroborate Dr. Boles' assertions.

For instance, the first notation by Dr. Goldstein concerning a *potential* mitochondrial problem in K.J.D. was in the notes of a neurology evaluation of May 21, 2013, where she noted as follows:

> [K.J.D.] has had labs "suggestive of mitochondrial disease", however we are not sure exactly what those labs are as they were done in the past, most likely at another institution.

(Ex. 24, p. 7, quotation marks in the original.) At that visit, Dr. Goldstein ordered mitochondrial testing to be done and noted that, if this testing came back negative, then she would order an epilepsy panel for K.J.D. (*Id*.) Apart from this remark that K.J.D.'s laboratory testing *possibly* suggested mitochondrial disease, however, medical records from Dr. Goldstein *do not reflect* any further instances of Dr. Goldstein's belief that K.J.D. suffered from a mitochondrial disorder. (*See generally* Exs. 24 and 37.)

Further, I note that Dr. Goldstein wrote a letter concerning K.J.D.'s case on February 6, 2014. (Ex. 24, p. 1.) This letter was written *nearly nine months after* the above-mentioned neurology consultation of May 21, 2013, during which Dr. Goldstein initially ordered a mitochondrial disorder lab test to be conducted on K.J.D. (Ex. 24, p. 1.) In her letter of February 6, 2014, however, Dr. Goldstein made *no mention of even the possibility of a mitochondrial disorder* in K.J.D. (*Id.*) In my view, Dr. Goldstein would have certainly commented on K.J.D.'s mitochondrial disorder if she did actually hold the belief, at the time of her medical opinion letter of February 6, 2014, that K.J.D. was suffering from such a disorder.

Moreover, concerning Dr. Boles' purported phone conversation with Dr. Goldstein concerning this matter, it is important to note that Dr. Goldstein did *not* provide a statement or affidavit supporting Dr. Boles' assertion that Dr. Goldstein agreed with Dr. Boles' assessment that K.J.D. had a mitochondrial disorder.

Thus, examining Dr. Goldstein's treatment evaluation notes and her medical opinion letter of February 6, 2014, I am doubtful of Dr. Boles' allegation as to Dr. Goldstein's alleged agreement with his assessment of a mitochondrial disorder/dysfunction diagnosis of K.J.D. The brief statement noted within Dr. Goldstein's treatment notes of May 2013 suggested only the *possibility* of a mitochondrial disease. I am not persuaded that Dr. Goldstein actually agreed with Dr. Boles' diagnosis of a mitochondrial disorder in K.J.D.

4. Conclusion concerning existence of "mitochondrial dysfunction"

Thus, for all the reasons detailed above, I find that Petitioners have failed to show that it is "more probable than not" that K.J.D. suffers from mitochondrial dysfunction.

D. In any event, Dr. Boles wholly failed to make a persuasive case that, even if K.J.D. has mitochondrial dysfunction, that fact would provide any support for the argument that the MMR vaccination injured K.J.D.

As noted above, at several points in his presentation Dr. Boles asserted that the existence of mitochondrial dysfunction in K.J.D. would have made him more susceptible to being injured by vaccinations. (*See* Ex. 25, p. 5, ¶ 7; Ex. 36, p. 3; 2-Tr. 225.) However, after reviewing both parties' expert reports and testimony, as well as the medical literature filed in this case, I find that Dr. Boles did *not* show that it is "more probable than not" that the existence of mitochondrial dysfunction in K.J.D. would have made him more susceptible to injury by vaccination.

Basically, I found that while Dr. Boles opined in summary fashion that mitochondrial dysfunction would make an individual more susceptible to injury by vaccination, he simply provided *virtually no evidence*, beyond his own unsupported assertions, that that would be true. In fact, Dr. Boles admitted that there are simply no studies on the issue of whether vaccines are safe for mitochondrial disease patients. (Ex. 36, p. 3.) He acknowledged that Dr. Raymond was correct in noting that there is "little data" available on this topic. (*Id*., p. 4.) At the evidentiary hearing, he admitted that Dr. Raymond was right that there is "no proof" supporting Dr. Boles' assertion concerning this issue. (2-Tr. 187.) And upon cross-examination, Dr. Boles acknowledged that he had previously written that "[t]he medical literature has absolutely no articles on immunizations/vaccinations in individuals with mitochondrial disease" (2-Tr. 210-11), and agreed that there still was "very much a dearth of literature" (2-Tr. 211) concerning this topic.

To be sure, Dr. Boles asserted that in his *personal experience* in treating patients with mitochondrial dysfunction, he perceived that mitochondrial dysfunction patients were more susceptible than others to vaccine injury. (*E.g.*, Ex. 36, pp. 3-4; 2-Tr. 187.) But Dr. Boles never explained that assertion at all, never gave any statistics about his own patients, nor even presented one example of a case under his care. I did not find his unexplained assertion in this regard to be credible or persuasive.

Meanwhile, Dr. Raymond opined that there is no good reason to conclude that mitochondrial dysfunction would make a person more susceptible to injury by vaccination. (*E.g.*, Ex. A, p. 5.)

On this issue, as in all factual issues, Petitioners have the burden of proof. I found that Dr. Boles' testimony, contradicted by Dr. Raymond, failed to successfully carry that burden. I find that there is no sufficient reason to believe that mitochondrial dysfunction makes a person more susceptible to injury by vaccinations. Accordingly, I find that even if I were to conclude that K.J.D. has mitochondrial dysfunction, that would *not* offer any significant support to a conclusion that K.J.D.'s *MMR vaccination* contributed to any of his tragic conditions.

E. Summary considering testimony concerning "mitochondrial dysfunction"

Concerning this issue, I acknowledge that since Dr. Boles has treated many persons with mitochondrial problems, he has relevant experience concerning this issue. After viewing the entire record, however, I conclude, for the reasons stated above, that Dr. Boles did not show that it was "more probable than not" that K.J.D. has mitochondrial dysfunction. Moreover, even if I were to assume that K.J.D. has mitochondrial dysfunction, I find that such a finding would not supply significant support to a conclusion that his *MMR vaccination* played any role in causing any of K.J.D.'s chronic disorders.

IX

THE EVIDENCE CONCERNING K.J.D.'S GENETIC VARIANT DID NOT ADD ANY SUPPORT TO THE CLAIM THAT THE MMR VACCINE INJURED K.J.D.

K.J.D. has been identified as having a genetic variant within his CACNA1H gene. (Ex. 21, p. 1.) The experts in this case sometimes referred to the CACNA1H gene as simply the "A1H" gene, and I will generally do so as well. (*See, e.g.*, 2-Tr. 146.) Dr. Boles discussed that genetic variant at length, and relied on it as part of his overall causation theory (*e.g.*, Ex. 25, pp. 4-6; Ex. 36, pp. 3-4; 2-Tr. 120-27, 142, 145-54, 164-68, 195-97), but after considering all of the evidence in the record concerning that variant, I do *not* find that the existence of the variant adds any support to the Petitioners' claim that the *MMR vaccine* caused any injury to K.J.D.

A. Dr. Boles' testimony

Dr. Boles opined in his expert report that it is "highly likely" that K.J.D.'s A1H variant predisposed him to "vaccine-related neurological disease." (Ex. 25, pp. 5-6.) Dr. Boles stated that persons with abnormal DNA sequences in "ion channel genes," such as the A1H gene, are said to have "channelopathies." (Ex. 25, p. 4, ¶ 3.) He explained that "ion channels" allow ions to cross cell membranes at a specifically regulated rate (2-Tr. 120; Ex. 25, p. 4, ¶¶ 3-4), and that "channelopathies" can alter the flow of ions (Ex. 25, p. 4, ¶ 4). He indicated that the A1H gene in particular governs *calcium* channels (2-Tr. 142), and that variants in such channels can result in improper flow of calcium across cell membranes in the brain, causing cell death in the brain or epilepsy (seizure disorder) (Ex. 25, p. 4, ¶ 4).

Dr. Boles indicated that he is unsure whether K.J.D. has an actual "channelopathy," but that it is likely that K.J.D. at least has "abnormalities" of his calcium channels, thereby contributing to his neurological conditions. (2-Tr. 127.) However, I note that Dr. Boles' confidence in his own theory seemed to shift between the expert reports that he submitted in this case and his testimony at the evidentiary hearing. That is, Dr. Boles stated in one expert report that it is "highly likely" that the A1H variant "constitutes a large portion of the genetic predisposition towards vaccine-related neurological disease in [K.J.D.]." (Ex. 25, pp. 5-6.) At the evidentiary hearing, however, he seemed to back away from the "highly likely" statement, concerning the alleged causal significance of the A1H variant in K.J.D.'s injuries. During the hearing, Dr. Boles deemed this variant to be merely "*one of many risk factors* which precipitated or allowed for" K.J.D.'s current condition. (2-Tr. 151, emphasis added.) In other words, Dr. Boles' opinion in this case went from a bold assertion that it was "highly likely" that the A1H variant was a part of the causation of K.J.D.'s neurological problems, to a mere suggestion that the variant was "one of many risk factors" for neurological deterioration.

B. Dr. Raymond's testimony

Dr. Raymond does not dispute that K.J.D. has the A1H variant. (Ex. A, p. 3.) However, he disputed that the existence of the A1H variant in K.J.D. offers any support to the theory that the *MMR vaccine* caused any harm to K.J.D. He explained that there exists no evidence that an A1H variant would make a person more susceptible to injury by vaccination -- indeed, he is unaware of any hypothesis as to how the variant might do so. (2-Tr. 249.)

C. Epilepsy and A1H variants

Dr. Boles pointed to studies suggesting that persons with A1H variants may be more likely than others to suffer from epilepsy. (Ex. 25, pp. 4-5, 2-Tr. 153.) And Dr. Raymond acknowledged that some studies may support an association between an A1H variant and absence epilepsy. (Ex. A, p. 4; 2-Tr. 245-46.) But the issue in this case is not whether K.J.D.'s *A1H variant* may have contributed to his epilepsy or other neurologic conditions. The issue is whether the *MMR vaccination* actually did contribute to any of K.J.D.'s conditions. And Dr. Boles did *not* point to any *evidence* indicating that the MMR vaccine can contribute to causing epilepsy, even in a person with an A1H variant.

Similarly, Dr. Boles argued that K.J.D.'s A1H disorder may have put him at risk not only for epilepsy, but for a broader neurologic deterioration. (*E.g.*, 2-Tr. 167-68.)[25] But again, Dr. Boles failed to point to *evidence* that the MMR vaccine can cause a person with an A1H variant to suffer neurologic deterioration, autism, or any of the tragic conditions that afflict K.J.D. (In fact, Dr. Boles acknowledged that he had looked for reports of the A1H gene interacting with vaccines to cause injury, but had *failed* to find any such reports. (2-Tr. 197.))

[25] However, it is noteworthy that when the Courtagen company, the very medical analysis company where Dr. Boles is employed, evaluated the A1H variant in K.J.D., the company's report stated that K.J.D.'s A1H variant was "probably a *benign* polymorphism." (Ex. 21, p. 6, emphasis added; *see also* 2-Tr. 195-96.)

D. Summary concerning the A1H variant testimony

In sum, while there is some evidence that an *A1H variant* might be contributory to epilepsy or other neurological problems, Petitioners presented no persuasive evidence that the presence of an A1H variant can make a person more susceptible to injury by the *MMR vaccine*.

X

DR. BOLES' ADMISSIONS AS TO THE TENTATIVE AND SPECULATIVE NATURE OF HIS OWN THEORIES

I also note that many of Dr. Boles' own statements acknowledged the *tentative* and *speculative* nature of various aspects of his causation theory. Actually, Dr. Boles, seemed merely to be *throwing out possibilities* as to the cause of K.J.D.'s conditions, yet failing to explain any of these opinions persuasively.

I have already discussed some such instances above. For example, I noted that concerning the topic of the A1H genetic variant, Dr. Boles went from first asserting that it was "highly likely" that the variant was involved in the causation of K.J.D.'s conditions, to simply suggesting that the variant was merely "one of many risk factors." (See Section IX(A), above.) However, I also provide some additional examples in this section.

At one point during the evidentiary hearing, while discussing the A1H variant, Dr. Boles admitted that his testimony concerning the A1H variant was merely a "very *plausible* mechanism that explains why it [K.J.D.'s deterioration] *might* have happened." (2-Tr. 190, emphasis added.) Further, Dr. Boles then acknowledged the speculative nature of his theory, admitting that the A1H variant "may or may not actually be the cause, and we don't have any proof that it is or it is not." (*Id.*) At that point, his theory suddenly, and without any further elaboration, shifted away from the A1H variant, to an unexplained assertion that there are "three variants in [K.J.D.'s] mitochondrial DNA," and that "every one of them is a plausible candidate, but I can't prove it." (*Id.*) (Dr. Boles, however, did not describe or discuss the alleged additional variants.)

Further, at another point in his hearing testimony, Dr. Boles admitted that he did not know the *mechanism*[26] of how the MMR vaccine might have acted to cause *K.J.D.'s* neurological/neurodevelopmental disabilities, in conjunction with his A1H variant and/or the

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[26] To be sure, a petitioner need *not* necessarily show the *mechanism* of injury. If a petitioner can show, based upon the overall record, that an injury was "more likely than not" caused by a vaccination, then that petitioner becomes entitled to a Program award whether or not the *mechanism* of injury is demonstrated. However, an expert's failure to point to a *mechanism* of injury can be *one factor* to consider in determining whether that expert's causation theory was persuasive. In this case, I found Dr. Boles' *overall presentation* to be speculative, dubious, and less persuasive than the presentation of Dr. Raymond. Based on the entire record, I do not find it to be "more probable than not" that K.J.D.'s MMR vaccine caused, or aggravated, any of K.J.D.'s conditions, by *any* mechanism.

alleged mitochondrial dysfunction. (2-Tr. 219.) Dr. Boles also acknowledged that Dr. Raymond was correct in stating that Dr. Boles' theory concerning the role of the A1H variant was "speculative." (Ex. 36, p. 3, ¶ 3.) In addition, while Dr. Boles opined at times in his testimony that K.J.D. suffered "absence seizures" in the form of staring episodes soon after his MMR vaccination, when asked to look at actual video of K.J.D. at the time, Dr. Boles again hesitated, stating that the episode in question "may or may not be a staring spell." (2-Tr. 181.)

Thus, as these examples illustrate, I found Dr. Boles' overall theory to be highly speculative, essentially an exercise in merely suggesting *potential* theories, without any persuasive evidence for them.

XI

DR. BOLES' DISCUSSION OF THE *MMR VACCINE'S* ALLEGED CONTRIBUTION TO CAUSING K.J.D.'S NEUROLOGICAL PROBLEMS WAS VERY BRIEF, WEAKLY EXPLAINED, AND COMPLETELY UNPERSUASIVE

Finally, I note that Dr. Boles' discussion of the alleged role of the *MMR vaccination* of October 25, 1999, as allegedly contributing to K.J.D.'s neurological disabilities, was very brief, weakly explained, and completely unpersuasive.

To be sure, Dr. Boles in his expert reports and hearing testimony did, very briefly, state a *conclusion* that K.J.D.'s MMR vaccination contributed to his neurological and neurodevelopmental disabilities. (*E.g.*, Ex. 25, p. 6, ¶ 1; 2-Tr. 120, 191.) However, it is telling that in both Dr. Boles' written reports and his hearing testimony, he presented almost *no* discussion, and even very few *mentions*, of the *MMR vaccination*. (*See, e.g.*, Ex. 25, p. 4, ¶ 2; 2-Tr. 158-59, 169-70.) The vast majority of his reports and testimony was devoted to discussing why K.J.D.'s *A1H genetic variant*, and his alleged *mitochondrial dysfunction*, may be risk factors for epilepsy and/or neurological disabilities. Petitioners and Dr. Boles pointed to no *evidence* demonstrating that the *MMR vaccine* in particular, or *any vaccinations*, can contribute to the causing of chronic epilepsy, autism, or other neurodevelopmental disorders.

Indeed, when asked by Petitioners' own counsel how K.J.D.'s vaccination of October 25, 1999, "triggered" neurological deterioration in K.J.D., in light of the A1H variant, Dr. Boles admitted that "[t]hat's a very good question, but there's not a simple answer for that." (2-Tr. 151-52.) Then, Dr. Boles said that "I would like to answer the second part of your question" -- *i.e.*, discuss the A1H variant. (2-Tr. 152.) But after discussing the A1H variant, Dr. Boles did not get around to directly answering the *first part* of counsel's question, concerning how the *vaccine* allegedly "triggered" K.J.D.'s conditions.

After that, Petitioners' counsel tried twice more to get Dr. Boles to describe "the specific risk of an MMR vaccine to a child with an A1H variant" (2-Tr. 158), and to explain why MMR can trigger neurologic deterioration in a person with an A1H variant (2-Tr. 169). But on neither occasion did Dr. Boles give an answer providing any significant support to his purported causation theory. Dr. Boles did not describe the alleged mechanism of causation that he had in mind. He did not point to any medical studies or literature showing that the MMR vaccine can

contribute to causing neurodevelopmental disabilities. Dr. Boles merely stated that in his own clinical practice he had seen a "large number of patients which have received putative vaccine-related injuries and which the parents very much thought that the child deteriorated at the time of vaccination" (2-Tr. 158), and later pointed to his clinical practice once again (2-Tr. 169-70).

Dr. Boles simply failed to point to any persuasive *evidence* that the MMR vaccination can contribute to the causation of neurological problems in persons with either or both mitochondrial dysfunction and/or an A1H genetic variant.[27]

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[27] I also note that in the "test case" opinions in the Omnibus Autism Proceeding, three different special masters considered in great detail (more than 600 pages) the specific question of whether there is any evidence that the *MMR vaccine* can cause or aggravate the neurodevelopmental disorder known as autism, and found that the evidence *strongly contradicts* the idea of MMR contributing to autism. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Further, in a number of decisions since that time, special masters have evaluated additional allegations that the MMR vaccine can cause or aggravate autism, and have unanimously found to the contrary. *See Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Fester v. HHS*, No. 10-243V, 2016 WL 1745436 (Fed. Cl. Spec. Mstr. Dorsey April 7, 2016) (autism not caused by measles, mumps, rubella, and varicella (MMRV) vaccine); *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Murphy v. HHS*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Corcoran Apr. 25, 2016) (autism not caused by DTaP or MMR vaccines), *aff'd*, 128 Fed. Cl. 348 (2016); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by MMR and other vaccines); *Allen v. HHS*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *Cunningham v. HHS*, No. 13-483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Hastings Aug. 1, 2016) (autism not caused by MMR vaccine), *aff'd*, (Fed. Cl. J. Smith Jan. 25, 2017); *Miller v. HHS*, No. 06-753V, 2012 WL 12507077 (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Anderson v. HHS*, No. 02-1314V, 2016 WL 8256278 (Fed. Cl. Spec. Mstr. Corcoran November 1, 2016) (autism not caused by MMR vaccination) (on review).

Instead, as noted above, Dr. Boles indicated that he based his theory that the MMR vaccination contributed to K.J.D.'s neurological/neurodevelopmental disabilities primarily on the assumption of a *temporal relationship* -- *i.e.*, on the factual assumptions that K.J.D. experienced an "abrupt," "sudden," and "dramatic" neurological deterioration, and the onset of "absence seizures," "shortly following" that MMR vaccination. (Ex. 25, pp. 3, 5; Ex. 30, pp. 1-2[28]). However, as set forth in detail in Section VII of this Decision, those factual assumptions were *incorrect*.[29]

In short, Dr. Boles has wholly failed to show that it is "more probable than not" that the *MMR* vaccine played any role in causing or aggravating K.J.D.'s tragic epilepsy, autism, and other neurodevelopmental conditions, or any of his chronic medical problems.[30]

XII

DR. GOLDSTEIN'S OPINION DOES NOT CHANGE MY CONCLUSION

As previously noted, Petitioners filed an opinion letter of Dr. Amy Goldstein, who was K.J.D.'s treating neurologist at one time. (*See* Ex. 24, p. 1.) Dr. Goldstein did not supply an affidavit, or testify at the evidentiary hearing. Instead, in a "Letter of Medical Necessity" dated February 6, 2014, Dr. Goldstein opined as follows:

> In my medical opinion as a child neurologist, I believe that [K.J.D.'s] mutations led to his susceptibility to vaccine injury and thus, developmental regression and epileptic encephalopathy, causing permanent neurodevelopmental disabilities.

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[28] *See also* 2-Tr. 163 ("This is a kid who was normal and then at one point in time significantly changed.")

[29] In addition, I note that Dr. Raymond explained that K.J.D.'s development was not atypical of a child with an ASD. (2-Tr. 235-36; 238.) He opined that K.J.D.'s stereotyped behaviors (*i.e.*, flapping of hands and spinning) and lack of social interaction manifested within the normal range (nine months to two years of age) usually seen within many children with ASDs. (2-Tr. 236-37.) He also stated that when K.J.D. began to "stare off," that was typical of autism, not an indication of absence seizures. (2-Tr. 238.) In other words, Dr. Raymond's testimony supports the view that there is no need to speculate, as Dr. Boles did, that the MMR vaccine had any causal connection to K.J.D.'s autism or any of his neurodevelopmental disabilities -- K.J.D.'s history is consistent with the development of a *typical* case of autism.

[30] Sadly, in addition to suffering from epilepsy, autism, and other neurologic/neurodevelopmental disabilities, K.J.D. also has suffered from gastrointestinal problems and other conditions. However, in their Amended Petition filed on December 30, 2014, and in their Prehearing Memorandum filed on December 18, 2015, Petitioners alleged only that K.J.D.'s neurological/neurodevelopmental conditions were vaccine-caused. And Dr. Boles, too, pointed only to K.J.D.'s neurological/neurodevelopmental conditions.

(Ex. 24, p. 1.) Therefore, Dr. Goldstein's letter seems to suggest that a combination of K.J.D.'s genetic "mutations" and a "vaccine injury" resulted in K.J.D.'s terrible neurodevelopmental disabilities. Dr. Goldstein's *curriculum vitae* was not submitted in this case; however, from the medical records submitted within the case, I gather that she is a pediatric neurologist, holds a position at the Children's Hospital of Pittsburgh, and has treated K.J.D. (Ex. 24, p. 1; *see generally* Ex. 37.) Accordingly, I have given her opinion careful consideration. However, in my final analysis, I find that Dr. Goldstein's opinion is strongly outweighed by the rest of the evidence in the record concerning the causation issue, particularly the testimony of Dr. Raymond.

Most importantly, I note that not only did Dr. Goldstein not submit an affidavit or testify, but she also did not set forth in her written opinion any detailed *explanation* concerning *why* she believes that K.J.D.'s neurodevelopmental disabilities were causally related to any vaccine. Her statement does not even mention *which* vaccination, on what date, she had in mind.

An additional reason to discount Dr. Goldstein's opinion, is that she did not state by *what mechanism* any vaccine might have caused injury to K.J.D., or *why* she thinks that any vaccines are capable of causing the severe neurodevelopmental disabilities from which K.J.D. suffers. Given these deficiencies in her opinion within her letter, I cannot conclude that she made a persuasive causation argument.

Furthermore, I must give Dr. Goldstein's opinion far less weight than the opinion of Dr. Raymond, who not only wrote a detailed report refuting Petitioners' causation assertion, but testified in order to *explain* his views at length, and was able to do so in a highly persuasive manner.

In short, while I have not ignored Dr. Goldstein's opinion letter, I found that it was strongly outweighed by all of the contrary evidence in this case.

XIII

PETITIONERS HAVE FAILED THE ALTHEN TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005)(citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits specifically within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy the *Althen* test.

A. Relationship between Althen Prongs 1 and 2

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccine *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, No. 01-60V, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, No. 96-518V, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, No. 02-738V, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, No. 06-120V, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the type of vaccination in question can cause the type of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the particular vaccination did cause the particular condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that any of the vaccines that K.J.D. received contributed to the causation of any of K.J.D.'s tragic neurodevelopmental conditions.

B. Petitioners have failed to establish Prong 1 of Althen in this case.

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. Petitioners in this case allege that the MMR vaccine contributed to the causation of K.J.D.'s neurological conditions in the context of his genetic A1H variant and/or his alleged underlying mitochondrial dysfunction. However, as discussed in Sections XIII, IX, X, and XI above, Petitioners have *not* demonstrated that K.J.D. even has mitochondrial dysfunction, and have *not come close* to demonstrating that the MMR vaccine can cause neurological injury in the context of either a genetic variant or an underlying mitochondrial dysfunction. As explained, the Petitioners' expert reports and expert testimony simply contained no significant scientific evidence establishing that the MMR vaccine can cause the types of neurological injuries that K.J.D. suffers from, under *any* circumstances. Thus, Petitioners' claim clearly fails under *Althen* Prong 1.

C. Petitioners have failed to establish Prong 2 of Althen in this case.

Under Prong 2, the Petitioners need to show that it is "more probable than not" that K.J.D.'s MMR vaccination *did* contribute to the causation of one or more of *K.J.D.'s own* neurologic conditions. But this they have failed to do, for all of the reasons detailed above. Having failed to demonstrate Prong 1, Petitioners logically cannot have shown Prong 2, for the same reasons. Further, as demonstrated in Section VII of this Decision, their claim must fail Prong 2 because Petitioners' expert relied upon *incorrect factual assumptions* about K.J.D.'s medical history. In addition, as explained above, the Petitioners also failed to demonstrate that K.J.D. even has mitochondrial dysfunction -- an important factual predicate for their causation opinion. (*See* Section VIII.) And my discussions in Sections IX, X, XI, and XII also demonstrate Petitioners' error as to Prong 2. Thus, Petitioners have failed to establish Prong 2 of *Althen* in this case.

D. Petitioners have failed to establish Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the first and second prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong. However, I note that as to Prong 3, under which Petitioners need to establish a proximate *temporal relationship* between the vaccination and the injury, I have demonstrated in Section VII above that Petitioners' expert made *incorrect* factual assumptions as to the temporal relationship between the MMR vaccination and (1) an alleged "sudden" and "abrupt" neurological deterioration in K.J.D., and (2) the onset of his seizures. Thus, Petitioners have clearly failed to establish Prong 3 as well.

E. This is not a close case.

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a

close case. For all the reasons set forth above, I found that Dr. Boles' theory was *not at all* persuasive, while Respondent's expert was *far* more persuasive.

XIV

WARNING TO PETITIONERS' COUNSEL IN CASES ALLEGING VACCINE-CAUSATION IN CONJUNCTION WITH AN ALLEGED MITOCHONDRIAL DISORDER, OR INVOLVING DR. BOLES

A. Cases involving alleged mitochondrial disorders and autism

In a number of cases recently, each involving a child with an ASD, expert witnesses for petitioners have based their causation theories on an allegation that the child suffers from a *mitochondrial* dysfunction or disorder. But in many of those cases, as in this case, there has been a lack of any persuasive evidence that the child even has any type of mitochondrial disorder. *See, e.g., Hardy v. HHS, supra*; *Coombs v. HHS, supra*; *Brook v. HHS, supra*; *Miller v. HHS, supra; Allen v. HHS, supra; R.K. v. HHS, supra; R.V. v. HHS, supra*.

In all those cases, there also has been a lack of persuasive evidence that even *genuine* mitochondrial disorders are of any relevance -- *i.e.*, as in this case, a lack of any persuasive evidence that the existence of a true mitochondrial disorder can make a child more susceptible to *the causation or aggravation of an ASD by vaccination*.

In this regard, I am aware that in *Paluck v. HHS*, 786 F.3d 1373 (Fed. Cir. 2015), the Court of Appeals affirmed a ruling that a particular child's mitochondrial disorder was significantly aggravated by receipt of several vaccines, thereby affecting the course of the child's neurodevelopmental disorder, which was not described as autism. I have also reviewed the medical article discussed in *Paluck*, by Jon S. Poling et al., *Developmental Regression and Mitochondrial Dysfunction in a Child with Autism*, 21(2) J. CHILD NEUROLOGY 170 (2006). (An abstract of this article was filed as Resp. Ex. A-8 in this case.) However, the facts in *Paluck* were quite different from the circumstances in any of the cases cited above. Moreover, in no case presented to me, nor in any of the cases cited above, has there been presented any persuasive evidence that even in a child with an actual mitochondrial disorder, *vaccines* can cause or aggravate that child's *ASD*.

Therefore, I strongly advise counsel in Vaccine Act cases to carefully *scrutinize*, for *credibility*, any cases in which an expert witness asserts that the existence of a *mitochondrial disorder* caused the child to be susceptible to causation or aggravation of an ASD, or other neurologic disorder, by vaccines. If, as in this case, and in the cases cited above in this Section XIV, there is no credible evidence that the child even suffers from a mitochondrial disorder, *I will be unlikely to find that the use of such expert was reasonable*, and thus compensable. Further, even in the context of an actual mitochondrial disorder, the expert must be able to supply *credible evidence* that a mitochondrial disorder can make a child susceptible to *causation or aggravation of an ASD* or other neurological disorder by vaccines, or else I may, again, be disinclined to compensate the attorney for presenting such expert.

B. Cases involving Dr. Boles

For the reasons described in detail above, I found Dr. Boles' presentation in this case to be extremely poorly explained, inconsistent, and totally unpersuasive. Therefore, I also warn Vaccine Act counsel of the possibility that, despite Dr. Boles' credentials in the area of mitochondrial disorders, use of Dr. Boles as an expert witness in the future may not be considered reasonable.

XV

CONCLUSION

The record of this case demonstrates plainly that K.J.D. and his family have been through a tragic ordeal, and I have great sympathy for the family. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by the Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on K.J.D.'s behalf.[31]

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

[31] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.